December 4, 2024

SELECT SUBCOMMITTEE ON THE

CORONAVIRUS PANDEMIC

CHAIRMAN BRAD WENSTRUP

AFTER ACTION REVIEW OF THE COVID-19 PANDEMIC:
The Lessons Learned and a Path Forward

Final Report of the

Select Subcommittee on the Coronavirus Pandemic
Committee on Oversight and Accountability

U.S. House of Representatives

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ONE HUNDRED EIGHTEENTH CONGRESS

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House of Representatives

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Dear Colleague:

It has been my distinct pleasure to lead the Select Subcommittee on the Coronavirus Pandemic for the 118th Congress. I was honored to be entrusted with a great responsibility: to investigate a once in 100-year pandemic and to prepare America for next time—and there will be a next time. This is a responsibility I took very seriously, and I believe that seriousness and teamwork has translated to much success.

Five years ago, on December 1, 2019, was what would eventually be the first confirmed case of COVID-19. After that, a pandemic devastated the world at nearly never before seen proportions, leaving millions dead and millions more concerned about long-term consequences.

COVID-19 was novel. The brightest scientists and medical experts were learning on the job to determine how to treat both the underlying disease and the second order side effects.

Since February 2023, the Select Subcommittee sought to produce a full after-action report to provide a road map of how we, in Congress, the Executive, and the private sector may better prepare for and respond to future pandemics. Throughout this process, the Select Subcommittee sent more than 100 investigative letters, conducted 38 transcribed interviews or depositions, held 25 hearings or meetings, and reviewed more than one million pages of documents from dozens of custodians. This work looks back on many events, comments, guidances, and other actions, to look forward. This is the single most thorough review of the pandemic conducted to date.

Most of you know me. You know I strive to work collegially, with our fellow Americans, to provide results for all of us. That is the same mentality I brought to my work as Chairman of the Select Subcommittee. During a time of intense partisanship, the Select Subcommittee had bipartisan consensus across multiple topics.

1) The possibility that COVID-19 emerged because of a laboratory or research related accident is not a conspiracy theory.

2) EcoHealth Alliance, Inc. and Dr. Peter Daszak should never again receive U.S. taxpayer dollars.

3) Scientific messaging must be clear and concise, backed by evidentiary support, and come from trusted messengers, such as front-line doctors treating patients.

4) Public health officials must work to regain American's trust; Americans want to be educated, not indoctrinated.

5) Former New York Governor Andrew Cuomo participated in medical malpractice and publicly covered up the total number of nursing home fatalities in New York.

In addition to these notable bipartisan successes, the Select Subcommittee developed extensive findings, some of which include:

1) The U.S. National Institutes of Health funded gain-of-function research at the Wuhan Institute of Virology.

2) The Chinese government, agencies within the U.S. Government, and some members of the international scientific community sought to cover-up facts concerning the origins of the pandemic.

3) Operation Warp Speed was a tremendous success and a model to build upon in the future. The vaccines, which are now probably better characterized as therapeutics, undoubtedly saved millions of lives by diminishing likelihood of severe disease and death.

4) Rampant fraud, waste, and abuse plagued the COVID-19 pandemic response.

5) Pandemic-era school closures will have enduring impact on generations of America's children and these closures were enabled by groups meant to serve those children.

6) The Constitution cannot be suspended in times of crisis and restrictions on freedoms sow distrust in public health.

7) The prescription cannot be worse than the disease, such as strict and overly broad lockdowns that led to predictable anguish and avoidable consequences.

Chairing the Select Subcommittee for the 118th Congress has been my honor. I said from the beginning, this work is the single most impactful responsibility I have undertaken in 12 years in Congress, and it has been. This work will help the United States, and the world, **predict** the next pandemic, **prepare** for the next pandemic, **protect** ourselves from the next pandemic, and hopefully **prevent** the next pandemic. Members of the 119th Congress should continue and build off this work, there is more information to find and honest actions to be taken.

The COVID-19 pandemic highlighted a distrust in leadership. Trust is earned. Accountability, transparency, honesty, and integrity will regain this trust. A future pandemic requires a whole of America response managed by those without personal benefit or bias. We can always do better, and for the sake of future generations of Americans, we must. It can be done!

Sincerely,

Brad Wenstrup, D.P.M.
Chairman

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Wuhan Institute of Virology [hereinafter "WIV"]

Office of Director of National Intelligence [hereinafter "ODNI"]

U.S. Department of Energy [hereinafter "DOE"]

Federal Bureau of Investigation [hereinafter "FBI"]

Dr. Robert Redfield [hereinafter "Dr. Redfield"]
Director
U.S. Centers for Disease Control and Prevention

The Honorable John Ratcliffe [hereinafter "Mr. Ratcliffe"]
Director
Central Intelligence Agency

Mr. Nicholas Wade [hereinafter "Mr. Wade"]
Former Science Editor
The New York Times

EcoHealth Alliance, Inc [hereinafter "EcoHealth"]

Defense Advanced Research Projects Agency [hereinafter "DARPA"]

Biosafety Level [hereinafter "BSL"]

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Former Director
Wellcome Trust

Dr. Francis Collins [hereinafter “Dr. Collins”]
Former Director
National Institutes of Health

Dr. Anthony Fauci [hereinafter “Dr. Fauci”]
Former Director
National Institute of Allergy and Infectious Diseases

Receptor Binding Domain [hereinafter “RBD”]

Mr. Greg Folkers [hereinafter “Mr. Folkers”]
Former Chief of Staff, Office of the Director
National Institute of Allery and Infectious Diseases

Dr. Lawrence Tabak [hereinafter Dr. Tabak”]
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National Institutes of Health

Defense Intelligence Agency [hereinafter "DIA"]

CDR Jean-Paul Chretien [hereinafter "CDR Chretien"]
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Defense Advanced Research Projects Agency

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National Institute of Allergy and Infectious Diseases [hereinafter "NIAID"]

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Chairman
House Oversight & Accountability Committee

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National Institute of Allergy and Infectious Disease

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Dr. Michael Lauer [hereinafter "Dr. Lauer"]
Deputy Director for Extramural Research
National Institutes of Health

U.S. Department of Justice [hereinafter "DOJ"]

Mr. F. Gray Handley [hereinafter "Mr. Handley"]
Associate Director
National Institute of Allery and Infectious Diseases

Freedom of Information Act [hereinafter "FOIA"]

Dr. David Morens [hereinafter "Dr. Morens"]
Senior Scientific Advisor to the Director
National Institute of Allergy and Infectious Diseases

Ms. Maragret Moore [hereinafter "Ms. Moore"]
Former Freedom of Information Act Public Liaison
National Institute of Allergy and Infectious Diseases

Coronavirus Aid, Relief, and Economic Security Act [hereinafter "CARES Act"]

Paycheck Protection Program [hereinafter "PPP"]

Economic Injury Disaster Loan Program [hereinafter "EIDL"]

Unemployment Insurance [hereinafter "UI"]

Pandemic Response Accountability Committee [hereinafter "PRAC"]

Inspector General [hereinafter "IG"]

American Rescue Plan Act [hereinafter "ARPA"]

President Joseph R. Biden [hereinafter "President Biden"]

U.S. Small Business Administration [hereinafter "SBA"]

Government Accountability Office [hereinafter "GAO"]

Personally Identifiable Information [hereinafter "PII"]

Social Security Number [hereinafter "SSN"]

U.S. Department of Homeland Security [hereinafter "DHA"]

Internal Revenue Service [hereinafter IRS"]

U.S. Department of Labor [hereinafter "DOL"]

Families First Coronavirus Response Act [hereinafter "FFCA"]

Federal Pandemic Unemployment Compensation [hereinafter "FPUC"]

Pandemic Emergency Unemployment Compensation [hereinafter "PEUC"]

Pandemic Unemployment Assistance [hereinafter "PUA"]

Employment and Training Administration [hereinafter "ETA"]

Coronavirus Preparedness and Response Supplemental Appropriations Act [hereinafter "CVPR"]

Employer Identification Numbers [hereinafter "EIN"]

U.S. Secret Service [hereinafter "USSS"]

U.S. Department of Treasury [hereinafter "Treasury"]

U.S. Department of Health and Human Services [hereinafter "HHS"]

Treasury Do Not Pay List [hereinafter "DNP list"]

Social Security Administration [hereinafter "SSA"]

Death Master File [hereinafter "DMF"]

Information Technology [hereinafter "IT"]

World Health Organization [hereinafter "WHO"]

United Nations [hereinafter "UN"]

Chinese Communist Party [hereinafter "CCP"]

Dr. Tedros Adhanom Ghebreyesus [hereinafter "Dr. Tedros"]
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International Health Regulations [hereinafter "IHR"]

Strategic National Stockpile [hereinafter "SNS"]

Personal Protective Equipment [hereinafter "PPE"]

Department of Defense [hereinafter "DOD"]

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Dr. Rochelle Walensky [hereinafter "Dr. Walensky"]
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Randomized Control Trial [hereinafter "RCT"]

Dr. Deborah Birx [hereinafter "Dr. Birx"]
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U.S. Food and Drug Administration [hereinafter "FDA"]

Emergency Use Authorization [hereinafter "EUA"]

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CEO
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The Honorable Andrew Bailey [hereinafter "Mr. Bailey"]
Attorney General
State of Missouri

Operation Warp Speed [hereinafter "OWS"]

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Former Principal Deputy Commissioner
U.S. Food and Drug Administration

Vice President Kamala Harris [hereinafter "Vice President Harris"]

Vaccines and Related Biological Products Advisory Committee [hereinafter "VRBPAC"]

Mr. Andrew Cuomo [hereinafter "Mr. Cuomo"]
Former Governor
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Dr. Howard Zucker [hereinafter "Dr. Zucker"]
Former Commissioner
New York State Department of Health

Greater New York Hospital Association [hereinafter "GNYHA"]

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Mr. Brad Hutton [hereinafter "Mr. Hutton"]
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Former Superintendent
New York State Department of Financial Services

Mr. Larry Schwartz [hereinafter "Mr. Schwartz"]
Former Senior Advisor to the Governor
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The Honorable Seema Verma [hereinafter "Ms. Verma"]
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Centers for Disease Control & Prevention

U.S. Centers for Medicare and Medicaid Services [hereinafter "CMS"]

Ms. Stephanie Benton [hereinafter "Ms. Benton"]
Former Executive Assistant to the Governor
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Dr. James Malatras [hereinafter "Dr. Malatras"]
Former Advisor to Governor Andrew Cuomo
State of New York

Mr. Garreth Rhodes [hereinafter "Mr. Rhodes"]
Former Deputy Superintendent
New York State Department of Financial Services

Dr. Eleanor Adams [hereinafter "Dr. Adams"]
Special Advisor
New York State Department of Health

Mr. Kenneth Raske [hereinafter "Mr. Raske"]
President & Chief Executive Officer
Greater New York Hospital Association

Mr. Michael Dowling [hereinafter "Mr. Dowling"]
President & Chief Executive Officer
Norwell Health

Ms. Farrah Kennedy [hereinafter "Ms. Kennedy"]
Former Executive Assistant to the Governor
New York State

The Honorable Brad Wenstrup [hereinafter "Chairman Wenstrup"]
Chairman
Select Subcommittee on the Coronavirus Pandemic

Advisory Committee on Immunization Practices [hereinafter "ACIP"]

Dr. Marion Gruber [hereinafter "Dr. Gruber"]
Former Director
Office of Vaccines Research and Review
U.S. Food and Drug Administration

Dr. Philip Krause [hereinafter "Dr. Krause"]
Former Director
Office of Vaccines Research and Review
U.S. Food and Drug Administration

Biologics License Application [hereinafter "BLA"]

Action Due Date [hereinafter "ADD"]

Dr. Peter Marks [hereinafter "Dr. Marks"]
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

Office of Vaccine Research and Review [hereinafter "OVRR"]

The Honorable Lloyd Austin [hereinafter "Secretary Austin"]
Secretary
U.S. Department of Defense

Dr. Cliff Lane [hereinafter "Dr. Lane"]
Deputy Director, Clinical Research
National Institutes of Health

Occupational Health and Safety Administration [hereinafter "OSHA"]

Dr. Kevin Bardosh [hereinafter "Dr. Bardosh"]
Affiliate Assistant Professor
University of Washington

Vaccine Adverse Event Reporting System [hereinafter "VAERS"]

Center for Biologics Evaluation and Research [hereinafter "CBER"]

Biologics Effectiveness and Safety [hereinafter "BEST"]

Vaccine Safety Datalink [hereinafter "VSD"]

Dr. Patrick Whelan [hereinafter "Dr. Whelan"]

Associate Clinical Professor of Pediatrics
Division of Rheumatology
University of California – Los Angeles

Informed Consent Action Network [hereinafter "ICAN"]

Vaccine Injury Compensation Program [hereinafter "VICP"]

Public Readiness and Emergency Preparedness [hereinafter "PREP"]

Countermeasures Injury Compensation Program [hereinafter "CICP"]

Health Resources and Services Administration [hereinafter "HRSA"]

Commander George Reed Grimes [hereinafter "CDR Grimes"]
Director
Division of Injury Compensation Programs
U.S. Health Resource & Services Administration

Small and Medium Enterprise [hereinafter "SME"]

Federal Reserve Board of Governors [hereinafter "Board of Governors"]

Federal Reserve Banks [hereinafter "Reserve Banks']

Federal Reserve Open Market Committee [hereinafter "FOMC"]

American Federation of Teachers [hereinafter "AFT"]

Ms. Randi Weingarten [hereinafter "Ms. Weingarten"]
President
American Federation of Teachers

Ms. Marla Ucelli-Kashyap [hereinafter "Ms. Ucelli-Kashyap"]
Director, Educational Issues
American Federation of Teachers

Dr. Greta Massetti [hereinafter "Dr. Massetti"]
Principal Deputy Director, Injury Center
Centers for Disease Control and Prevention

Ms. Kelly Nedrow (Trautner) [hereinafter "Ms. Nedrow (Trautner)"]
Director, Health Issues
American Federation of Teachers

Ms. Carole Johnson [hereinafter "Ms. Johnson"]

Administrator
Health Resources and Services Administration

National Education Association [hereinafter "NEA"]

The Honorable Melanie Egorin [hereinafter "Ms. Egorin"]
Assistant Secretary for Legislation
U.S. Department of Health and Human Services

Dr. Gerald Keusch [hereinafter "Dr. Keusch"]
Professor of Medicine and International Health
Boston University

Dr. Robert Kessler [hereinafter "Dr. Kessler"]
Communications Manager
EcoHealth Alliance, Inc.

II. List of Hearings and Meetings

February 28, 2023
"Preparing for the Future by Learning From the Past: Examining COVID Policy Decisions"
Witnesses: 1) Dr. Jay Bhattacharya M.D., Ph.D.
Professor of Medicine
Stanford University

2)Dr. Martin Kulldorff Ph.D.
Professor of Medicine
Harvard University

3) Dr. Martin Makary M.D., M.P.H.
Chief, Islet Transplant Surgery / Professor of Surgery
Johns Hopkins University

4) Dr. Georges Benjamin M.D. (Minority Witness)
Executive Director
American Public Health Association

March 8, 2023
"Investigating the Origins of COVID-19"
Witnesses: 1) Dr. Jamie Metzl
Senior Fellow
Atlantic Council

2) Dr. Robert Redfield
Former Director
U.S. Centers for Disease Control and Prevention

3) Mr. Nicholas Wade
Former Editor for *Nature* and *Science*
Former Science Editor for *The New York Times*

4) Dr. Paul Atwater (Minority Witness)
Clinical Director, Division of Infectious Diseases
Sherrilyn and Ken Fisher Professor of Medicine
Johns Hopkins School of Medicine

March 28, 2023
"The Consequences of School Closures: Intended and Unintended"
Witnesses: 1) Mr. David Zweig
Author and Investigative Journalist
The Atlantic, *New York Magazine*, and *The Free Press*

2) Dr. Tracy Høeg
Physical Medicine & Rehabilitation Specialist
Epidemiologist
Private Practice Physician

3) Ms. Virginia Gentles
Director, Education Freedom Center
Inpednant Women's Forum

4) Ms. Donna Mazyck (Minority Witness)
Executive Director
National Association of School Nurses

April 18, 2023
"Investigating the Origins of COVID-19, Part 2: China and the Available Intelligence"
Witnesses: 1) The Honorable John Ratcliffe
Former Director of National Intelligence
Office of the Director of National Intelligence

2) Mr. David Feith
Former Deputy Assistant Secretary of State, East Asian and Pacific Affairs
U.S. Department of State

3) Dr. Mark Lowenthal (Minority Witness)
Former Assistant Director of Central Intelligence of Analysis and Production
Former Vice Chairman for Evaluation for the National Intelligence Council
Former Deputy Assistant Secretary of State for Intelligence and Research

April 26, 2023
"The Consequences of School Closures, Part 2: The President of the American Federation of Teachers Ms. Randi Weingarten"
Witness: 1) Ms. Randi Weingarten
President
American Federation of Teachers

May 11, 2023
"Investigating Pandemic Immunity: Acquired, Therapeutic, or both"
Witnesses: 1) Dr. Marty Makary
Chief, Islet Transplant Surgery
Professor of Surgery
Johns Hopkins University

2) Dr. Margery Smelkinson

3) Dr. Tina Tan (Minority Witness)
Professor of Pediatric Infectious Diseases
Feinberg School of Medicine
Northwestern University

May 17, 2023
"'Like Fire Through Dry Grass': Nursing Home Mortality & COVID-19 Policies"
Witnesses: 1) Ms. Janice Dean

2) Mr. Bill Hammond
Senior Fellow for Health Policy
Empire Center

3) Ms. Vivian Zayas
Voices for Seniors

4) Dr. David Grabowski (Minority Witness)
Professor of Health Care Policy
Harvard Medical School

June 13, 2023
"Oversight of CDC Policies and Decisions During the COVID-19 Pandemic"
Witness: 1) Dr. Rochelle Walensky
Director
U.S. Centers for Disease Control and Prevention

June 21, 2023
"Churches vs. Casinos: The Constitution is Not Suspended in Times of Crisis"
Witnesses: 1) The Honorable Andrew Bailey
Attorney General
Missouri

2) The Honorable Elizabeth Murrill
Solicitor General
Louisiana

3) Mr. Misha Tseytlin
Partner
Troutman Pepper Hamilton Sanders LLP

4) Mr. Micah Schwartzman (Minority Witness)
Hardly Cross Dillard Professor of Law
Director, Karsh Center for Law and Democracy
University of Virginia School of Law

July 11, 2023
"Investigating the Proximal Origin of a Cover Up"
Witnesses: 1) Dr. Kristian Andersen
Professor
Scripps Research

2) Dr. Robert Garry
Professor
Tulane University School of Medicine

3) Dr. W. Ian Lipkin (Attendance Excused)
John Snow Professor of Epidemiology
Columbia University

4) Dr. Andrew Rambaut (Declined to Attend)
Professor
University of Edinburgh

5) Dr. Edward Holmes (Declined to Attend)
Professor of Virology
University of Sydney

July 27, 2023
"Because I Said So: Examining the Science and Impact of COVID-19 Vaccine Mandates"
Witnesses: 1) Dr. Kevin Bardosh
Affiliate Assistant Professor
University of Washington

2) Ms. Allison Williams
Reporter
Fox Sports

3) Ms. Danielle Runyan
Senior Counsel
First Liberty

4) Dr. John Lynch (Minority Witness)
Associate Professor of Medicine and Allergy and Infectious Diseases
University of Washington School of Medicine

September 14, 2023
"Oh Doctor, Where Art Thou? Pandemic Erosion of the Doctor-Patient Relationship"
Witnesses: 1) Dr. Azedeh Khatibi
Physician
Medical Ethics and Freedom Advocate

2) Dr. Jeffrey Singer
Surgeon
Senior Fellow
CATO Institute, Department of Health Policy Studies

3) Dr. Jerry Williams
Founder
Urgent Care 24/7

4) Dr. Andrea Shane (Minority Witness)
Professor of Pediatrics
Division of Infectious Disease
Emory University School of Medicine

September 19, 2023
"The Strategic National Stockpile" **Classified**
Witnesses: 1) The Honorable Dawn O'Connell
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

2) Mr. Steven Adams
Deputy Assistant Secretary
Center for the Strategic National Stockpile
U.S. Department of Health and Human Services

3) Ms. Julia Limage
Director
Office of Strategy, Policy, and Requirements
Administration for Strategic Preparedness and Response
U.S. Department of Health and Human Services

December 13, 2023
"Reforming the WHO: Ensuring Global Health Security and Accountability"
Witnesses: 1) The Honorable Atul Gawande
Assistant Administrator for Global Health
U.S. Agency for International Development

2) The Honorable John Nkengasong
Ambassador-at-Large
U.S. Global AIDS Coordinator
Senior Bureau Official for Global Health Security and Diplomacy
U.S. Department of State

3) Ms. Loyce Pace
Assistant Secretary for Global Affairs
U.S. Department of Health and Human Services

January 31, 2024
"Overseeing the Department of Health and Human Services' Compliance with Congress"
Witness: 1) The Honorbale Melanie Egorin
Assistant Secretary for Legislation
U.S. Department of Health and Human Services

February 15, 2024
"Assessing America's Vaccine Safety Systems, Part 1"
Witnesses: 1) Dr. Daniel Jernigan
Director
National Center for Emerging and Zoonotic Infectious Diseases
U.S. Centers for Disease Control and Prevention

2) CDR George Reed Grimes
Director
Division of Injury Compensation Programs
U.S. Health Resource & Services Administration

3) Dr. Peter Marks
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

March 6, 2024
"Examining the White House's Role in Pandemic Preparedness and Response"
Witness: 1) Maj. Gen. (ret.) Paul Friedrichs
Director
Office of Pandemic Preparedness and Response Policy
The White House

March 21, 2024
"Assessing America's Vaccine Safety Systems, Part 2"
Witnesses: 1) Ms. Renee Gentry
Director, Vaccine Injury Litigation Clinic
George Washington University

2) Dr. David Gortler
Senior Research Fellow
Public Health Policy and Regulation
The Heritage Foundation

3) Dr. Patrick Whelan
Associate Clinical Professor of Pediatrics
Division of Rheumatology
University of California – Los Angeles

4) Dr. Yvonne Maldonado (Minority Witness)
Chief of the Division of Infectious Diseases
Department of Pediatrics
Stanford University School of Medicine

April 16, 2024
"Academic Malpractice: Examining the Relationship Between Scientific Journals, the Government, and Peer Review"
Witnesses: 1) Dr. Holden Thorp
Editor-in-Chief
Science Journals
American Association for the Advancement of Science

2) Mr. Richard Horton (Declined to Attend)
Editor-in-Chief
The Lancet

3) Dr. Magdalena Skipper (Declined to Attend)
Editor-in-Chief
Nature

May 1, 2024
"A Hearing with the President of EcoHealth Alliance, Dr. Peter Daszak"
Witness: 1) Dr. Peter Daszak
President
EcoHealth Alliance, Inc.

May 16, 2024
"Overseeing the Overseers: A Hearing with NIH Deputy Director, Dr. Lawrence Tabak"
Witness: 1) Dr. Lawrence Tabak
Principal Deputy Director
National Institutes of Health

May 22, 2024
"A Hearing with the National Institute of Allergy and Infectious Diseases Senior Scientific Advisor, Dr. David Morens"
Witness: 1) Dr. David Morens
Senior Scientific Advisor to the Director
National Institute of Allergy and Infectious Diseases

June 3, 2024
"A Hearing with Dr. Anthony Fauci"
Witness: 1) Dr. Anthony Fauci
Former Director
National Institute of Allergy and Infectious Diseases

September 10, 2024
"A Hearing with former New York Governor Andrew Cuomo"
Witness: 1) The Honorable Andrew Cuomo
Former Governor
New York

November 14, 2024
"Preparing for the Next Pandemic: Lessons Learned and the Path Forward"
Witness: 1) Dr. Lawrence Tabak
Principal Deputy Director
National Institutes of Health

2) Dr. Henry Walke
Director
Office of Readiness and Response
U.S. Centers for Disease Control and Prevention

3) Dr. Hillary Marston
Chief Medical Officer
U.S. Food and Drug Administration

III. List of Transcribed Interviews and Depositions

April 6, 2023:	Dr. Ian Lipkin John Snow Professor of Epidemiology Columbia University
April 21, 2023:	Dr. Michael Farzan Professor of Pediatrics Harvard Medical School
June 9, 2023:	Dr. Robert Garry Professor Tulane University School of Medicine
June 16, 2023:	Dr. Kristian Andersen Professor Scripps Research
June 20, 2023:	Ms. Marla Ucelli-Kashyap Director, Educational Issues American Federation of Teachers
June 23, 2023:	Ms. Kelly Nedrow Director, Health Issues American Federation of Teachers
June 29, 2023:	CDR Jean-Paul Chretien Program Manager, Biological Technologies Office Defense Advanced Research Projects Agency
October 31, 2023:	Dr. Gretta Massetti Principal Deputy Director, Injury Center Centers for Disease Control and Prevention
November 2, 2023:	Dr. Michael Lauer Deputy Director for Extramural Research National Institutes of Health
November 13, 2023:	Dr. Erik Stemmy Team Lead, Influenza Research and Response National Institute of Allergy and Infectious Disease
November 14, 2023:	Dr. Peter Daszak President EcoHealth Alliance, Inc.

November 28, 2023:	Dr. Emily Erbelding Director, Division of Microbiology and Infectious Diseases National Institute of Allery and Infectious Diseases
December 8, 2023:	Mr. F. Gray Handley Associate Director National Institute of Allery and Infectious Diseases
December 12, 2023:	Mr. Greg Folkers Former Chief of Staff, Office of the Director National Institute of Allery and Infectious Diseases
December 15, 2023:	Dr. Clifford Lane Deputy Director, Clinical Research National Institutes of Health
December 18, 2023:	Dr. Howard Zucker Former Commissioner New York State Department of Health
December 20, 2023:	Dr. Hugh Auchincloss Former Acting Director National Institute of Allergy and Infectious Diseases
December 29, 2023:	Dr. David Morens Senior Scientific Advisor to the Director National Institute of Allergy and Infectious Diseases
January 5, 2024:	Dr. Lawrence Tabak Principal Deputy Director National Institutes of Health
January 8 & 9, 2024:	Dr. Anthony Fauci Former Director National Institute of Allergy and Infectious Diseases
January 12, 2024:	Dr. Francis Collins Former Director National Institutes of Health
January 18, 2024:	Dr. David Morens Senior Scientific Advisor to the Director National Institute of Allergy and Infectious Diseases

January 22, 2024:	Dr. Ralph Baric Professor, Department of Epidemiology University of North Carolina at Chapel Hill
April 8, 2024:	Dr. Eleanor Adams Special Advisor New York State Department of Health
May 3, 2024:	Mr. Garreth Rhodes Former Deputy Superintendent New York State Department of Financial Services
May 9, 2024:	Dr. James Gimlett Program Manager Defense Advanced Research Projects Agency
May 13, 2024:	Dr. Janet Woodcock Former Principal Deputy Commissioner U.S. Food and Drug Administration
May 20, 2024:	Dr. James Malatras Former Advisor to Governor Andrew Cuomo State of New York
May 30, 2024:	Ms. Beth Garvey Former Counsel to the Governor State of New York
May 31, 2024:	Ms. Linda Lacewell Former Superintendent New York State Department of Financial Services
June 11, 2024:	The Honorable Andrew Cuomo Former Governor State of New York
June 24, 2024:	Ms. Melissa DeRosa Former Secretary to the Governor State of New York
June 24, 2024:	Mr. Lawrence Schwartz Former Senior Advisor to the Governor State of New York
August 13, 2024:	Dr. Jeffrey Sturchio *In his capacity as* Consultant

	EcoHealth Alliance, Inc.
August 27, 2024:	Mr. Bradley Hutton Former Deputy Commissioner New York State Department of Health
October 4, 2024:	Ms. Margaret Moore Former Freedom of Information Act Public Liaison National Institute of Allergy and Infectious Diseases
October 8, 2024:	Ms. Farrah Kennedy Former Executive Assistant to the Governor New York State
October 10, 2024:	Dr. Peter Hotez Professor Baylor College of Medicine

IV. On-the-Ground Oversight

November 6, 2023 – November 8, 2023
STAFFDEL

- Los Alamos, New Mexico
    - Los Alamos National Laboratory

- Livermore, California
    - Lawrence Livermore National Laboratory

February 19, 2024 – February 24, 2024
CODEL Wenstrup Europe

- Geneva, Switzerland
    - World Health Organization Headquarters

- Paris, France
    - French National Academy of Medicine
    - World Organization of Animal Health

- Brussels, Belgium
    - North Atlantic Treaty Organization Headquarters
    - European External Action Service
    - European Commission's Directorate-General for Health and Food Safety

August 18, 2024 – August 25, 2024
CODEL Wenstrup S.E. Asia

- Taipei, Taiwan
    - Office of the President
    - Office of the Vice President
    - Ministry of Foreign Affairs
    - Ministry of Health and Welfare
    - Academica Sineca

- Phnom Penh, Cambodia
    - Ministry of Health
    - Institut Pasteur du Cambodge
    - Live Bird Market Surveillance

- Vientiane, Laos
    - Ministry of Health
    - National Animal Health Laboratory
    - National Center for Laboratory and Epidemiology
    - Live Bird Market Surveillance

The Origins of the Coronavirus Pandemic, Including but Not Limited to the Federal Government's Funding of Gain-of-Function Research

I. The Unknown Origins of COVID-19

FINDING: SARS-CoV-2, the Virus that Causes COVID-19, Likely Emerged Because of a Laboratory or Research Related Accident.

Four years after the onset of the worst pandemic in 100 years, the weight of the evidence increasingly supports the lab leak hypothesis. Since the Select Subcommittee commenced its work in February 2023, more and more senior intelligence officials, politicians, science editors, and scientists increasingly have endorsed the hypothesis that COVID-19[1] emerged as the result of a laboratory or research related accident.

In January 2021, the State Department published an unclassified Fact Sheet entitled, "Fact Sheet: activity at the Wuhan Institute of Virology," [hereinafter "Fact Sheet"] that stated the following.

1) "The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illness."[2] The June 2023 ODNI Assessment entitled, "Potential Links Between the Wuhan Institute of Virology and the Origin of the COVID-19 Pandemic," [hereinafter "June 2023 ODNI Assessment"] supported this conclusion.[3]

2) "The WIV has a published record of conducting "gain-of-function" research to engineer chimeric viruses."[4] The June 2023 ODNI Assessment supported this conclusion and went further, stating, "[s]cientists at the WIV have created chimeras, or combinations of SARS-like coronaviruses through genetic engineering, attempted to clone other unrelated viruses, and used reverse genetic cloning techniques on SARS-like coronaviruses."[5] The June 2023 ODNI Assessment continued, "[s]ome of the WIV's genetic engineering projects on coronaviruses involved techniques that could make it difficult to detect intentional changes."[6]

3) "Despite the WIV presenting itself as a civilian institution, the United States had determined that the WIV collaborated on publications and secret projects with China's military…since at least 2017."[7] Again, the June 2023 ODNI Assessment supported this

[1] Throught this Report, "COVID-19" is used to describe SARS-CoV-2.
[2] FACT SHEET: ACTIVITY AT THE WUHAN INSTITUTE OF VIROLOGY, U.S. DEP'T OF STATE (Jan. 15, 2021) [hereinafter "Fact Sheet"].
[3] POTENTIAL LINKS BETWEEN THE WUHAN INSTITUTE OF VIROLOGY AND THE ORIGIN OF THE COVID-19 PANDEMIC, OFFICE OF THE DIR. OF NAT'L INTELLIGENCE (June 2023) [hereinafter "June 2023 ODNI Assessment"].
[4] Fact Sheet, *supra* note 2.
[5] June 2023 ODNI Assessment, *supra* note 3.
[6] *Id.*
[7] Fact Sheet, *supra* note 2.

conclusion, stating, "…WIV personnel have worked with scientists associated with the PLA on public health-related projects and collaborated on biosafety and biosecurity projects."[8]

Further, the June 2023 ODNI Assessment stated, "[s]ome WIV researchers probably did not use adequate biosafety precautions at least some of the time prior to the pandemic in handling SARS-like coronaviruses, increasing the risk of accidental exposure to viruses."[9]

In February and March of 2023, DOE and FBI publicly acknowledged their respective assessments that COVID-19 was the likely result of a lab incident—FBI with moderate confidence and DOE with low confidence.[10] Other intelligence elements assess COVID-19's emergence was likely zoonotic, albeit all with low confidence.[11]

On March 8, 2023, Dr. Redfield testified:

Dr. Robert Redfield (March 8, 2023)

From the earliest days of the pandemic, my view was that both theories about the origin of COVID-19 needed to be aggressively and thoroughly examined. Based on my initial analysis of the data, I came to believe—and still believe today—that it indicates COVID-19 infections more likely were the result of an accidental lab leak than the result of a natural spillover event. This conclusion is based primarily on the biology of the virus itself, including its rapid high infectivity for human-to-human transmission which would then predict rapid evolution of new variants, as well as a number of other important factors to include the unusual actions in and around Wuhan in the fall of 2019…[12]

One month later in April 2023, Mr. Ratcliffe testified:

The Honorable John Ratcliffe (April 18, 2023)

First, let me state the bottom-line up front. My informed assessment as a person with as much access as anyone to our government's intelligence during the initial year of the pandemic has been and continues to be that a lab leak is the only explanation credibly supported by our intelligence, by science, and by commonsense. From a view inside the IC, if our intelligence and evidence supporting a lab leak theory was placed side-by-

[8] June 2023 ODNI Assessment, *supra* note 3.
[9] *Id.*
[10] Hannah Rabinowitz, *FBI Director Wray acknowledges bureau assessment that Covid-19 likely resulted from lab incident*, CNN (updated Mar. 1, 2023); Jeremy Herb & Natasha Bertrand, *US Energy Department assesses Covid-19 likely resulted from lab leak, furthering US intel divide over virus origi*n, CNN (Feb. 27, 2023).
[11] June 2023 ODNI Assessment, *supra* note 3.
[12] Investigating the Origins of COVID: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong, 1, (Mar. 8, 2023) [hereinafter "Investigating the Origins of COVID-19"].

> side with our intelligence and evidence pointing to a natural origins or spillover theory, the lab leak side of the ledger would be long, convincing, even overwhelming, while the spillover side would be nearly empty and tenuous.[13]

In January 2024, Mr. Wade voiced his increasing support for a lab incident origin.[14] Mr. Wade astutely noted that "SARS2 possesses a furin cleavage site, found in none of the other 871 known members of its viral family, so it cannot have gained such a site through the ordinary evolutionary swaps of genetic material within a family."[15] With the natural evolution of a furin cleavage site being nonexistent, Mr. Wade further noted that EcoHealth and the WIV's DEFUSE proposal, which was rejected by DARPA, sought to do what nature had not been ever known to do—insert a furin cleavage site into a SARS2 virus.[16] It is, therefore, more than just a coincidence that COVID-19 emerged from the city with a lab preparing to conduct this research under cost-effective yet risky BSL-2 protocols.[17]

In June 2024, Dr. Chan explained five key points that support the lab leak scenario as more plausible than a zoonotic spillover.[18]

First, COVID-19 emerged in Wuhan, the city that happens to be the location of the China's foremost research lab for SARS-like viruses.[19] Dr. Shi, has been researching SARS-like viruses for over a decade and even initially wondered if the outbreak came from the WIV.[20]

Next, in 2018, a year before the outbreak, EcoHealth, in partnership with the WIV, in a grant application to DARPA proposed to create a virus with SARS-CoV-2's defining features. In their application to DARPA, EcoHealth and its WIV partners stated their intent to create a SARS-like virus with a furin cleavage site, which is the exact same feature that made humans susceptible to COVID-19 infection.[21]

Third, the WIV has a track record of engaging in this type of airborne viral research under low biosafety conditions.[22] At the WIV, it was known that Chinese researchers conducted this type of research under BSL-2 protocols, which do not require masking at all times and involves less protective equipment.[23] In the U.S., this type of research would be conducted under BSL-3 protocols, which require stricter personal respirator use at all times and more protective

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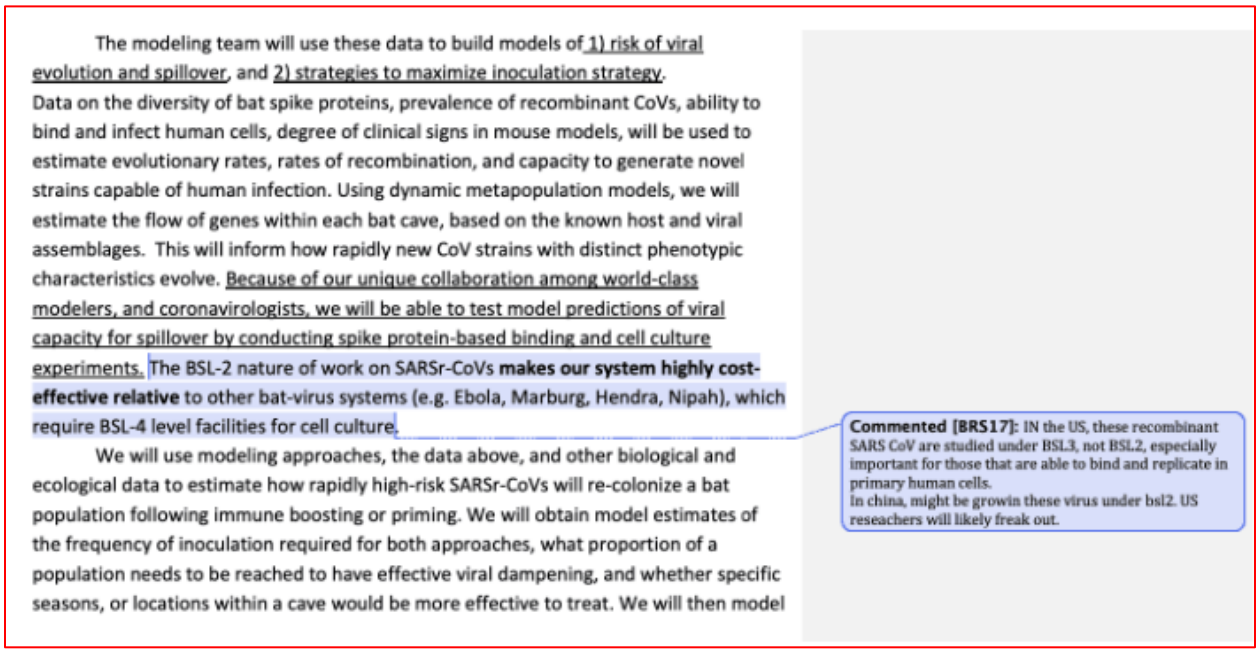
[13] Investigating the Origins of COVID Part 2: China and the Available Intelligence: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong, 1, (Apr. 18, 2023) [hereinafter "Investigating the Origins of COVID Part 2: China and the Available Intelligence"].
[14] Nicholas Wade, *The Story of the Decade*, CITY JOURNAL (Jan. 25, 2024).
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] Alina Chan, *Why the Pandemic Probably Started in a Lab, in 5 Key Points*, THE N.Y. TIMES (June 3, 2024) [hereinafter "Chan"].
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*

equipment.[24] In fact, in a draft proposal for the grant to DARPA, Dr. Daszak acknowledged that some of the SARS-CoV-2 research would be conducted at BSL-2 at the WIV.[25]



The modeling team will use these data to build models of 1) risk of viral evolution and spillover, and 2) strategies to maximize inoculation strategy. Data on the diversity of bat spike proteins, prevalence of recombinant CoVs, ability to bind and infect human cells, degree of clinical signs in mouse models, will be used to estimate evolutionary rates, rates of recombination, and capacity to generate novel strains capable of human infection. Using dynamic metapopulation models, we will estimate the flow of genes within each bat cave, based on the known host and viral assemblages. This will inform how rapidly new CoV strains with distinct phenotypic characteristics evolve. Because of our unique collaboration among world-class modelers, and coronavirologists, we will be able to test model predictions of viral capacity for spillover by conducting spike protein-based binding and cell culture experiments. The BSL-2 nature of work on SARSr-CoVs **makes our system highly cost-effective relative** to other bat-virus systems (e.g. Ebola, Marburg, Hendra, Nipah), which require BSL-4 level facilities for cell culture.

We will use modeling approaches, the data above, and other biological and ecological data to estimate how rapidly high-risk SARSr-CoVs will re-colonize a bat population following immune boosting or priming. We will obtain model estimates of the frequency of inoculation required for both approaches, what proportion of a population needs to be reached to have effective viral dampening, and whether specific seasons, or locations within a cave would be more effective to treat. We will then model

Commented [BRS17]: IN the US, these recombinant SARS CoV are studied under BSL3, not BSL2, especially important for those that are able to bind and replicate in primary human cells.
In china, might be growin these virus under bsl2. US reseachers will likely freak out.

Fourth, the evidence supporting that COVID-19 came from an animal at the Huanan Seafood Market in Wuhan is tenuous.[26] Dr. Chan points of that "the existing genetic and early case data show that all known COVID-19 cases probably stem from a single introduction of SARS-CoV-2 into people, and the outbreak at the Wuhan market probably happened after the virus had already been circulating in humans."[27] Furthermore, no infected animal has been verified at the Wuhan market or its supply chain.[28]

Finally, key evidence that would be expected if the virus had emerged from the wildlife trade is still missing.[29] In previous outbreaks, such as SARS in 2002 and MERS in 2012, infected animals were found, the earliest cases occurred in people exposed to live animals, and ancestral variants of the virus found in animals were discovered, but none of this evidence has been discovered for COVID-19.[30]

In September 2024, Mr. Boris Johnson, former British Prime Minister, stated his belief that the COVID-19 pandemic originated via a laboratory or research related accident in Wuhan.[31]

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[24] *Id.*
[25] Emily Kopp, *American scientists misled Pentagon on research at the Wuhan Institute of Virology*, U.S. RIGHT TO KNOW (Dec. 18, 2023).
[26] Chan, *supra* note 18.
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] Jane Dalton, *Boris Johnson claims Covid originated in lab, in sudden U-turn in his views*, INDEPENDENT (Sept. 29, 2024).

Mr. Johnson noted that the pandemic "now looks overwhelmingly likely that the mutation was the result of some botched experiment in a Chinese lab."[32]

In November 2024, Biden-Harris Administration COVID-19 Response Coordinator, Dr. Ashish K. Jha, wrote that Chinese "senior military officers have been writing for years about the potential benefits of offensive biological warfare."[33] He also acknowledged that the COVID-19 virus might have accidentally leaked from a lab.[34]

On November 21, 2024, Dr. Tim Spector, Professor at King's College London, who played a significant role in the pandemic response in the United Kingdom, recently doubled down on his belief that the lab leak is the most likely source of the pandemic.[35] Dr. Spector noted that "[i]t's looking increasingly like that was a bit of a cover-up and the most likely source of this was a lab leak from Wuhan."[36]

Over the course of the pandemic, there have also been studies suggesting COVID-19's emergence was zoonotic and transferred from an animal to a human.[37] Dr. Lipkin described two of these studies as "armchair epidemiology,"[38] Dr. Baric described one as having a "major problem,"[39] and Dr. Holden Thorp, the Editor-in-Chief of *Science* (the publisher of two of these studies) testified these studies "do not conclusively prove [ ] the theory of natural origin."[40]

As Mr. Ratcliffe testified, the ledger on the side of lab leak is full of convincing evidence while the spillover side is nearly empty. Since January 2020, the body of evidence has only grown stronger in support of a lab leak theory.

FINDING:	"The Proximal Origin of SARS-CoV-2" Was "Prompted" by Dr. Anthony Fauci to "Disprove" the Lab Leak Theory.

On February 16, 2020, Dr. Rambaut, on behalf of himself and his co-authors, Dr. Andersen, Dr. Lipkin, Dr. Holmes, and Dr. Garry posted "The Proximal Origin of SARS-CoV-2"

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[32] *Id.*
[33] Ashish K. Jha, *et al., The U.S. could soon face a threat 'more powerful' than nuclear weapons*, THE WASH. POST (Nov. 11, 2024).
[34] *Id.*
[35] Sarah Knapton, *Lab leak most likely source of Covid, says Prof Tim Spector,* THE TELEGRAPH (Nov. 21, 2024).
[36] *Id.*
[37] Alexander Crits-Christoph, *et. al., Genetic tracing of market wildlife and viruses at the epicenter of the COVID-19 pandemic*, CELL 187: 5468-5482; Edward Holmes, *et. al., The origins of SARS-CoV-2: A critical review*, CELL 184: 4848-4856; Jonthan Pekar, *et. al., The molecular epidemiology of multiple zoonotic origins of SARS-CoV*-2, SCIENCE 377:960-966; Michael Worobey, *et. al., The Hunan Seafood Wholesale Market in Wuhan was the early epicenter of the COVID1-9* pandemic, SCIENCE 377: 951-959; Edward Holmes, *et. al., The emergence and evolution of SARS-CoV-2*, ANN. REV. VIROL. (Sept. 11, 2024).
[38] Transcribed Interview of Ian Lipkin, M.D., John Snow Professor of Epidemiology, Columbia Univ. (Apr. 6, 2023) [hereinafter "Lipkin TI"].
[39] Transcribed Interview of Ralph Baric, Ph.D., Professor, University of N. Carolina, at 102 (Jan. 22, 2024) [hereinafter "Baric TI"].
[40] Academic Malpractice: Examining the Relationship Between Scientific Journals, the Government, and Peer Review: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong, (Apr. 11, 202) (Statement of Dr. Holden Thorp, Editor-in-Chief, Science Journals).

on the website *Virological*.[41] One month later, on March 17, 2020, "The proximal origin of SARS-CoV-2" [hereinafter "Proximal Origin"] was published in *Nature Medicine*.[42]

The authors of Proximal Origin stated two primary conclusions: (1) "…[COVID-19] is not a laboratory construct or a purposefully manipulated virus," and (2) "we do not believe that any type of laboratory-based scenario is plausible."[43]

January 2020

According to Dr. Farrar, the initial discussions regarding the sequence of COVID-19 and any unusual aspects began on January 8 or 9.[44] At that point it is unclear what the concerns were or who exactly was involved, however e-mails suggest that Dr. Farrar called both Chinese officials and Dr. Collins.[45]

Message

From: Jeremy Farrar [redacted]
Sent: 7/28/2020 12:36:51 AM
To: Edward Holmes [redacted]
CC: Kristian G. Andersen [redacted] Fauci, Anthony (NIH/NIAID) [E] [redacted]
Subject: Re: The authors who wrote the paper saying that SARS-CoV-2 is not human engineered first tried convincing Anthony Fauci of the opposite.

Thanks Eddie.

I will recheck emails and phones, I will try and do that today.

I think it really starts on the 8/9th January and the calls you and I had with China and the original sequence.

And others were also on those calls – Francis Collins, Mike Ferguson, Patrick Vallance.

I would suggest we get the sequence of events absolutely right before replying.

Best wishes Jeremy

According to Dr. Farrar he became aware of "chatter" suggesting the virus looked almost engineered to infect human cells in the last week of January.[46] In Dr. Farrar's own words, "[t]hat got my mind racing. This was a brand-new virus that seemingly sprang from nowhere. Except

[41] Kristian Andersen, Ph.D., *et. al., The Proximal Origin of SARS-CoV-2*, VIROLOGICAL (Feb. 16, 2020), https://virological.org/t/the-proximal-origin-of-sars-cov-2/398.
[42] Kristian Andersen, Ph.D., *et. al., The proximal origin of SARS-CoV-2*, NATURE MEDICINE (Mar. 17, 2020) [hereinafter "Proximal Origin"].
[43] *Id.*
[44] E-Mail from Jeremy Farrar, Dir., Wellcome Trust, to Eddie Holmes, Ph.D., Professor, University of Sydney, *et. al.* (July 28, 2020, 12:36 AM).
[45] *Id*. (Dr. Collins did not recall being on any calls with Chinese officials or Dr. Farrar, separately or together, during this time period.).
[46] Jeremy Farrar, Spike: The Virus vs. The People – The Inside Story (Profile Books 2021) [hereinafter "Spike: The Virus vs. The People – The Inside Story"].

that this pathogen had surfaced in Wuhan, a city with a BSL-4 virology lab which is home to an almost unrivalled collection of bat viruses."[47] Dr. Farrar's first concern was, "[c]ould the novel-coronavirus be anything to do with 'gain-of-function' (GOF) studies?"[48] This is a type of research that Dr. Farrar, much like Dr. Fauci, believed to be "ultimately useful."[49]

Around this same time, Dr. Andersen shared his concerns regarding the possibility the COVID-19 pandemic was the result of a lab leak and that it had properties that may have been genetically modified or engineered—specifically the furin cleavage site—with Dr. Holmes.[50] According to Dr. Holmes, Dr. Andersen texted, "Eddie, can we talk? I need to be pulled off a ledge here."[51]

Dr. Andersen went on to express concerns regarding two distinct aspects of the virus—the RBD and the furin cleavage site. Dr. Andersen also found a paper written by Dr. Baric and Dr. Shi [hereinafter "Baric/Shi Paper"] that purported to have inserted furin cleavage sites into SARS. As recounted by Dr. Farrar, this paper was a "how-to-manual for building the Wuhan coronavirus in a laboratory."[52] Dr. Holmes responded, "fuck, this is bad" and "oh my god what worse words than that."[53]

On January 30, 2020, Dr. Holmes relayed Dr. Andersen's concerns to Dr. Farrar via his burner phone.[54] Dr. Andersen recalled Dr. Holmes saying that Dr. Farrar acted as Dr. Holmes' "handler."[55] Then, as Dr. Holmes characterized it, the conversations went from "zero to 100."[56]

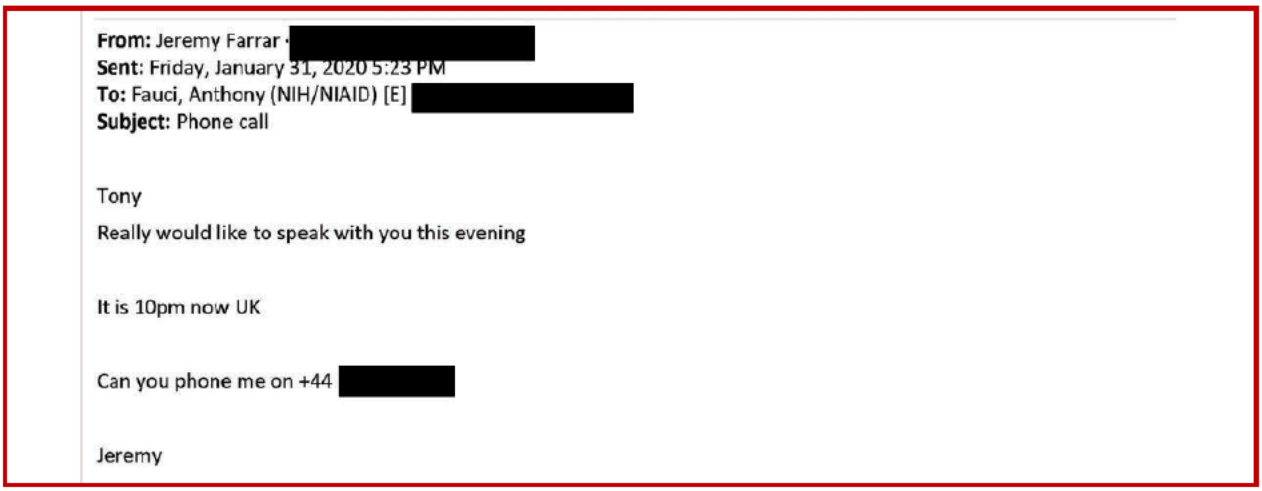
January 31, 2020

In a transcribed interview, Dr. Andersen testified that after discussing his concerns with Dr. Farrar, they began to organize a conference call [hereinafter "February 1 Conference Call"].[57] The February 1 Conference Call was a forum for Dr. Andersen to "walk through my concerns and then…discuss it."[58]

> **Dr. Kristian Andersen (June 16, 2023)**
>
> And Jeremy [Farrar] gets all of this set up. He, I'm sure, has been in touch with Tony Fauci at the time, reaches out to Dr. Fauci, asks him to call me.[59]

[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] Vincent Racaniello, This Week in Virology 940 (Sept. 28, 2022) [hereinafter "Racaniello"].
[51] *Id.*
[52] Spike: The Virus vs. the People, *supra* note 46.
[53] *Id;* Racaniello, *supra* note 50.
[54] *Id.*
[55] Transcribed Interview of Kristian Andersen, Ph.D., Professor, Scripps Research, at 16 (June 16, 2023) (hereinafter "Andersen TI").
[56] Racaniello, *supra* note 50.
[57] Andersen TI, *supra* note 55, at 16.
[58] *Id.*
[59] *Id.*

It is unclear whether Dr. Farrar and Dr. Fauci had significant contact prior to the call, but it was at this point that Dr. Farrar alerted Dr. Fauci to potential concerns and they began orchestrating a conference call.[60] Dr. Fauci's assistant replied, "Will call shortly…"[61]



From: Jeremy Farrar [redacted]
Sent: Friday, January 31, 2020 5:23 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]
Subject: Phone call

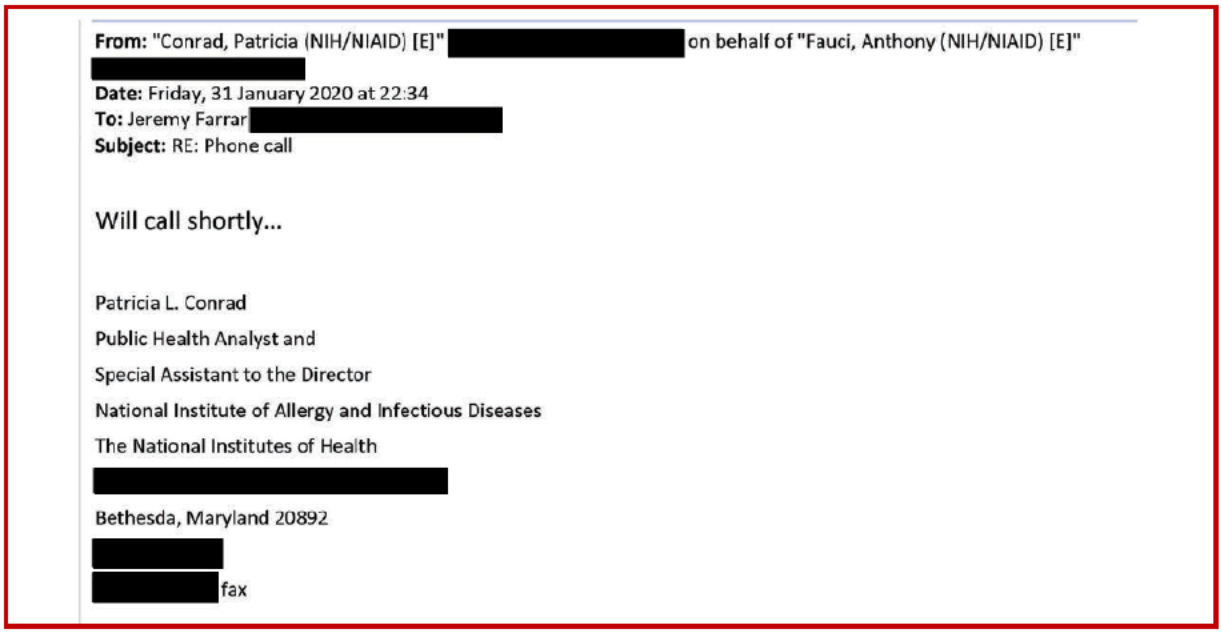
Tony

Really would like to speak with you this evening

It is 10pm now UK

Can you phone me on +44 [redacted]

Jeremy



From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted] on behalf of "Fauci, Anthony (NIH/NIAID) [E]" [redacted]
Date: Friday, 31 January 2020 at 22:34
To: Jeremy Farrar [redacted]
Subject: RE: Phone call

Will call shortly...

Patricia L. Conrad
Public Health Analyst and
Special Assistant to the Director
National Institute of Allergy and Infectious Diseases
The National Institutes of Health
[redacted]
Bethesda, Maryland 20892
[redacted]
[redacted] fax

Presumably, Dr. Fauci and Dr. Farrar discussed the concerns raised by Dr. Andersen and Dr. Holmes because after their call, Dr. Farrar responds to Dr. Fauci and asks him to call Dr. Andersen, stating, "[t]he people involved are: Kristian Andersen…, Bob Garry…, Eddie Holmes."[62]

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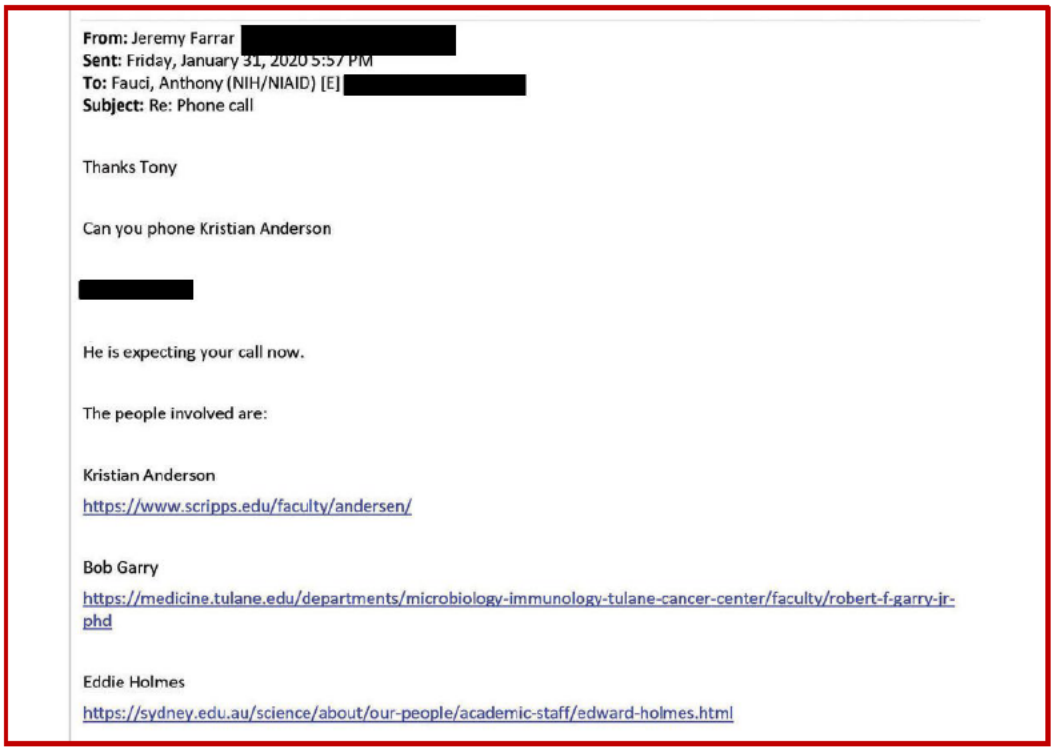
[60] E-Mail from Jeremy Farrar, Ph.D., Dir., Wellcome Trust, to Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Jan. 31, 2020, 5:23 PM).
[61] E-Mail from Patricia Conrad, Special Asst. to the Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Jeremy Farrar, Ph.D., Dir., Wellcome Trust (Jan. 31, 2020, 22:34).
[62] E-Mail from Jeremy Farrar, Ph.D., Dir., Wellcome Trust, to Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Jan. 31, 2020, 5:57 PM).



From: Jeremy Farrar [redacted]
Sent: Friday, January 31, 2020 5:57 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]
Subject: Re: Phone call

Thanks Tony

Can you phone Kristian Anderson

[redacted]

He is expecting your call now.

The people involved are:

Kristian Anderson
https://www.scripps.edu/faculty/andersen/

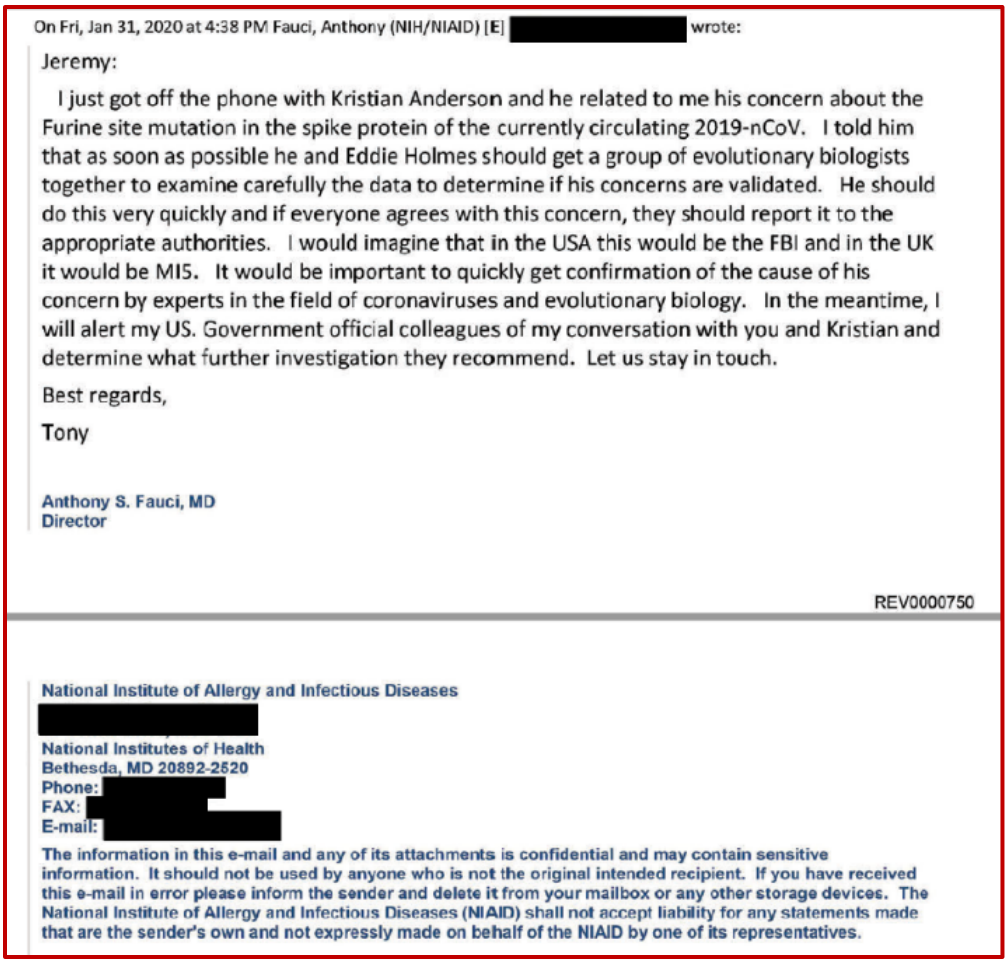
Bob Garry
https://medicine.tulane.edu/departments/microbiology-immunology-tulane-cancer-center/faculty/robert-f-garry-jr-phd

Eddie Holmes
https://sydney.edu.au/science/about/our-people/academic-staff/edward-holmes.html

Dr. Fauci memorialized his January 31, 2020 conversation with Dr. Andersen.[63] In this e-mail, Dr. Fauci raised direct concerns regarding the furin cleavage site, directed Dr. Andersen to "get a group of evolutionary biologists together to examine carefully the data to determine if his concerns are validated," and stated that if there is a possibility COVID-19 came from a lab leak, they would need to "report it to the appropriate authorities."[64] This appears to be Dr. Fauci's first mention of setting up a conference call and drafting a report. Dr. Fauci concluded by saying, "…I will alert my U.S. Government official colleagues of my conversation…and determine what further investigation they recommend."[65]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[63] E-Mail from Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Jeremy Farrar, Ph.D., Dir., Wellcome Trust, & Kristian Andersen, Ph.D., Professor, Scripps Research (Jan. 31, 2020, 4:38 PM).
[64] *Id.*
[65] *Id.*



On Fri, Jan 31, 2020 at 4:38 PM Fauci, Anthony (NIH/NIAID) [E] [redacted] wrote:

Jeremy:

I just got off the phone with Kristian Anderson and he related to me his concern about the Furine site mutation in the spike protein of the currently circulating 2019-nCoV. I told him that as soon as possible he and Eddie Holmes should get a group of evolutionary biologists together to examine carefully the data to determine if his concerns are validated. He should do this very quickly and if everyone agrees with this concern, they should report it to the appropriate authorities. I would imagine that in the USA this would be the FBI and in the UK it would be MI5. It would be important to quickly get confirmation of the cause of his concern by experts in the field of coronaviruses and evolutionary biology. In the meantime, I will alert my US. Government official colleagues of my conversation with you and Kristian and determine what further investigation they recommend. Let us stay in touch.

Best regards,

Tony

Anthony S. Fauci, MD
Director

REV0000750

National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]

The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

Dr. Andersen testified that January 31 was the first time he spoke to Dr. Fauci personally, outside of potential interactions at conferences.[66] Accordingly, it was also on the January 31 phone call between Dr. Fauci and Dr. Andersen when the first discussion of a paper regarding a possible lab leak took place.[67]

Dr. Kristian Andersen (June 16, 2023)

Q. Was this the first time that you had ever spoken to Dr. Fauci, like personally?

A. Probably. Yeah…

Q. Outside of conferences or - -?

A. Sure. Yes. Yes. Yes. Absolutely, yes.

***

[66] Andersen TI, *supra* note 55, at 16.
[67] *Id.*

> Q. So, I think you testified, and you can correct me if this isn't a fair characterization, that Dr. Fauci suggested a peer-reviewed paper of some kind. When did that suggestion happen?
>
> A. That happened - - again, the first phone call I had with him, which was immediately prior - - I think a day prior [January 31], right, to the conference call itself [February 1] where I relayed my initial concerns and findings. He specifically suggested considering writing a peer-reviewed publication on it, and specifically I remember hearing him saying that if you think this came from a lab, you should write this up as a peer-reviewed paper, so it can be judged by the peer community basically, yeah.[68]

Then, Mr. Folkers forwarded Dr. Fauci an article entitled, "Mining coronavirus genomes for clues to the outbreak's origins."[69] This article directly mentions the Baric/Shi Paper that Dr. Andersen found alarming, and links directly EcoHealth to the WIV.[70] Dr. Fauci forwarded the article to Dr. Farrar and Dr. Andersen and said, "[t]his just came out today. You may have seen it. If not, it is of interest to the current discussion."[71] Dr. Andersen responded:[72]

> **From:** Kristian G. Andersen [redacted]
> **Sent:** Friday, January 31, 2020 10:32 PM
> **To:** Fauci, Anthony (NIH/NIAID) [E] [redacted]
> **Cc:** Jeremy Farrar [redacted]
> **Subject:** Re: FW: Science: Mining coronavirus genomes for clues to the outbreak's origins
>
> Hi Tony,
>
> Thanks for sharing. Yes, I saw this earlier today and both Eddie and myself are actually quoted in it. It's a great article, but the problem is that our phylogenetic analyses aren't able to answer whether the sequences are unusual at individual residues, except if they are completely off. On a phylogenetic tree the virus looks totally normal and the close clustering with bats suggest that bats serve as the reservoir. The unusual features of the virus make up a really small part of the genome (<0.1%) so one has to look really closely at all the sequences to see that some of the features (potentially) look engineered.
>
> We have a good team lined up to look very critically at this, so we should know much more at the end of the weekend. I should mention that after discussions earlier today, Eddie, Bob, Mike, and myself all find the genome inconsistent with expectations from evolutionary theory. But we have to look at this much more closely and there are still further analyses to be done, so those opinions could still change.
>
> Best,
> Kristian

[68] *Id.*
[69] E-Mail from Greg Folkers, Chief of Staff, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Jan. 31, 2020); Jon Cohen, *Mining coronavirus genomes for clues to the outbreaks' origins*, SCIENCE (Jan. 31, 2020).
[70] Jon Cohen, *Mining coronavirus genomes for clues to the outbreaks' origins*, SCIENCE (Jan. 31, 2020).
[71] E-Mail from Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Jeremy Farrar, Ph.D., Dir., Wellcome Trust, & Kristian Andersen, Ph.D., Professor, Scripps Research (Jan. 31, 2020).
[72] E-Mail from Kristian Andersen, Ph.D., Professor, Scripps Research, to Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Jeremy Farrar, Ph.D., Dir., Wellcome Trust (Jan. 31, 2020, 10:32 PM).

Dr. Andersen clarified what "unusual features" he was referencing.

Dr. Kristian Andersen (June 16, 2023)

Q. Which features, at that time, were you talking about?

A. Yeah, I'm talking about, like, the furin cleavage site, the receptor binding domain, and a few things associated with that, the BamH1 restriction site that I mentioned, as well as some features associated with that - - basically, what I ended up presenting the next day at that conference call.[73]

Dr. Andersen subsequently confirmed that when he said the "genome inconsistent with expectations from evolutionary theory" he meant he thought COVID-19 could have been engineered.

Dr. Kristian Andersen (June 16, 2023)

Q. …[W]as it the furin cleavage site and the RBD that looked inconsistent from evolutionary theory?

***

A. And when I'm saying the genome is inconsistent with expectations from evolutionary theory, it's a bit of ***a fancy way of basically saying, like, look, guys, I think this could be engineered.***[74]

The next day, February 1, 2020, a group of scientists, including Dr. Fauci, gathered via conference call for Dr. Andersen to present these findings and discuss a path forward.

February 1, 2020

On February 1, 2020, Dr. Farrar emailed a large group to set up the February 1 Conference Call to discuss Dr. Andersen's concerns about the origins of COVID-19. The original attendee list included:

Kristian Andersen
Bob Garry
Christian Drosten
Tony Fauci
Mike Ferguson
Ron Fouchier
Eddie Holmes

[73] Andersen TI, *supra* note 55, at 16.
[74] *Id.*

Marion Koopmans
Stefan Pohlmann
Andrew Rambaut
Paul Schreier
Patrick Vallance.[75]

Despite Dr. Farrar sending the invitation on February 1, Dr. Andersen testified he was aware of the potential of a call prior to February 1.

Dr. Kristian Andersen (June 16, 2023)

Q. When did you first learn of this call? Was it when the roster was sent out, February 1st?

A. No. I knew that the call was going to happen, because Eddie, myself had talked about it, and I talked to Jeremy Farrar…This is where I became aware of all the details surrounding the conference call.[76]

In a transcribed interview, Dr. Garry testified he was also aware of the potential conference call prior to February 1.

Dr. Robert Garry (June 9, 2023)

Q. How were you invited to this call?

A. I believe I received an email from Jeremy Farrar.

Q. …[T]o the best of you recollection, what day was that?

A. Probably the day before or - - at most 2 days before, but I think it was the day before.[77]

In addition to Dr. Fauci, at least two other federal government officials were on the call despite not being on the official roster—Dr. Collins and Dr. Tabak.

E-mails suggest that Dr. Fauci personally invited Dr. Collins.[78]

[75] E-Mail from Jeremy Farrar, Ph.D., Dir., Wellcome Trust, to Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, *et. al.* (Feb. 1, 2020).
[76] Andersen TI, *supra* note 55, at 16.
[77] Transcribed Interview of Robert Garry, Ph.D., Professor, Tulane University School of Medicine, at 16 (June 9, 2023) [hereinafter "Garry TI"].
[78] E-Mail from Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Jeremy Farrar, Ph.D., Dir., Wellcome Trust, & Francis Collins, M.D., Ph.D., Dir., Nat'l Insts. of Health (Feb. 1, 2020, 15:48); E-Mail from Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Robert Garry, Ph.D., Professor, Tulane School of Medicine, *et. al.* (Feb. 1, 2020, 15:50).

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]>
Date: Saturday, 1 February 2020 at 15:48
To: Jeremy Farrar [redacted]
Cc: Francis Collins [redacted]
Subject: RE: Teleconference

Jeremy:
Francis will be on the call. He is trying to phone you.
Tony

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]
Date: Saturday, 1 February 2020 at 15:50
To: "Garry, Robert F" [redacted] Jeremy Farrar [redacted]
Cc: Patrick Vallance [redacted], "Drosten, Christian" [redacted], Marion Koopmans [redacted] Edward Holmes [redacted] "Kristian G. Andersen" [redacted], Paul Schreier [redacted], Michael FMedSci [redacted] Francis Collins [redacted] "Tabak, Lawrence (NIH/OD) [E]" [redacted]
Subject: RE: Teleconference

Please include Francis Collins (copied here) on all subsequent correspondence regarding this call. Thanks.

On March 24, 2023, the Select Subcommittee requested Dr. Fauci clarify whether he personally invited Dr. Collins to the conference call.[79] On March 27, 2023, Dr. Fauci responded, via Counsel, "[a]s one would reasonably expect, Dr. Fauci advised his immediate supervisor, Dr. Francis Collins, that the call was taking place. Dr. Collins expressed an interest in joining the call."[80] In a transcribed interview, Dr. Fauci further clarified this sequence of events.

Dr. Anthony Fauci (January 9, 2024)

Q. So I want to talk about the first forward of yours to Dr. Collins. Did Dr. Collins request to be on the call? Like, how did the process -- you obviously forwarded the call-in details to Dr. Collins. How did that process play out?

A. Well, Dr. Collins is my boss. So this seemed like a pretty important call for NIH, so I thought it would be a good idea to let my boss know.

[79] Letter from Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, to Anthony Fauci, M.D. Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Mar. 24, 2023).
[80] Letter from David Schertler & Danny Ornato, Counsel for Dr. Anthony S. Fauci, to Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic (Mar. 27, 2023).

Q. So you got invited -- or you had the January 31st call, got invited to the conference call after Farrar set it all up, and then went and was like, "Dr. Collins, there's this call happening. Would you like to take part?" Is that fair?

A. I believe that's the way it went, because -- yeah, I believe that's the way it went.

Q. Okay. It's been in the news for a while and Dr. Redfield has talked about this a lot and testified in front of us in March that he was not included in the call. He was very clear to say he was not -- he's not testifying that he was intentionally excluded, just that he was not included. At any point, did –

A. Actually, he said that I kept him out of the call because he had a different viewpoint.

Q. He did say that –

A. He said that clearly.

Q. Do you recall having any conversations with –

A. Sorry.

Q. No. No problem. Do you recall having any conversations with Dr. Redfield about the call?

A. No. No.

Q. Why not?

A. Because why would I do that? This was a call that was organized by Jeremy Farrar, who was the organizer of the call, and it wasn't my call who was in and on. But it was perfectly appropriate for me to notify my boss.

Q. This is the beginning of a pandemic, discussing how to respond to the pandemic.

A. Yeah. Yeah.

Q. Dr. Redfield is the head of the CDC –

A. No, I'm sorry, I disagree with you.

Q. Okay.

A. I disagree with you completely. It is my responsibility to notify my boss. The next morning, I notified the chief of staff of the Department of Health and Human Services, who is the chief of staff to the Secretary, who is Bob Redfield's boss.

Q. Did you have any conversations with Dr. Redfield after the fact regarding the call?

A. I don't recall.[81]

Dr. Tabak was also on the February 1 Conference Call.[82]

Message

From: Mike Ferguson [redacted]
Sent: 2/9/2020 12:00:46 PM
To: Jeremy Farrar [redacted] Edward Holmes [redacted] kga1978 [redacted]
Andrew Rambaut [redacted] rfgarry [redacted]
CC: r.fouchier [redacted] P.Vallance1 [redacted] collinsf [redacted] afauci [redacted] Josie Golding [redacted] m.koopmans [redacted] christian.drosten [redacted]
Subject: Re: 2019 N-CoV
Attachments: Summary.Feb7_MF.pdf

Dear Jeremy et al

I have made some comments and suggestions on the pdf attached.

I am not an expert on protein O-glycosylation - however, Dr Tabak, who was on the call last weekend, is and if I were to consult anyone else on this it would be Henrik Clausen
https://icmm.ku.dk/english/research-groups/clausen-group/

Dr. Lawrence Tabak (January 5, 2024)

Q. …And I don't - - we don't know - - I don't know if Dr. Fauci ever responded, but did you end up on the February 1st conference call?

A. I did.[83]

Dr. Andersen testified to what he presented on the February 1 conference call.

[81] Transcribed Interview of Anthony Fauci, M.D., former Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, at 61-63 (Jan. 9, 2024) [hereinafter "Fauci TI 2"].
[82] E-Mail from Mike Ferguson, Professor, University of Dundee, to Jeremy Farrar, Ph.D., Dir., Wellcome Trust. *et. al.* (Feb. 9, 2020, 12:00 PM).
[83] Transcribed Interview of Lawrence A. Tabak, D.D.S., Ph.D., Principal Dep. Dir., Nat'l Insts. of Health, at 133 (Jan. 5, 2024) [hereinafter "Tabak TI"].

Dr. Kristian Andersen (June 16, 2023)

Q. And what, to the best of your recollection, and briefly, what did you present on the call?

A. I presented the main findings I had, which was some of the features that I found to be unusual in the viral genome, including the receptor binding domain, the furin cleavage site, the damage, one site which is a restriction site, and also just outlining some of the research that have been ongoing at the Wuhan Institute of Virology. And I had a presentation, which you have as part of your exhibits too.

Q. Regarding the Wuhan Institute of Virology, what did you present?

A. Just in broad terms, the fact that they were culturing viruses from bats, or attempting to culture viruses from bats, isolate viruses from bat samples, which is not easy, in BSL-2; and, also, some of their chimeric work using WIV-1, for example, which is a common backbone that they are using; as well as just the general strategies around creating chimeric viruses, much of which I believe was done in BSL-2 and, as I mentioned, animal work in BSL-3. But those were my, sort of, concerns around the research and the reason, of course, for why we need to consider a potential lab leak as a scientific hypothesis, yes.[84]

Dr. Andersen further testified that the primary participants on the call were himself, Dr. Rambaut, Dr. Holmes, Dr. Christian Drosten,[85] Dr. Ron Fouchier,[86] and Dr. Marion Koopmans.[87, 88] Both Dr. Garry and Dr. Andersen testified about any comments made by Dr. Fauci or Dr. Collins on the February 1 Conference Call.

Dr. Robert Garry (June 9, 2023)

Q. Did [Dr. Fauci] say anything?

A. He didn't say a whole a lot.

Q. To your recollection - - what did he say?

[84] Garry TI, *supra* note 77, at 89-90.
[85] Dr. Christian Drosten: Professor, Deputy Coordinator Emerging Infections, German Center for Infection Research, DE.
[86] Dr. Ron Fouchier: Deputy Head of the Erasmus MC Department of Viroscience, Erasmus MC, NL.
[87] Dr. Marion Koopmans: Head of the Erasmus MC Department of Viroscience, Erasmus MC, NL.
[88] Andersen TI, *supra* note 55, at 98.

A. He just acknowledged that he was there, but the details are not really clear. He really didn't say much of substance. It was, you know -- I mean, Jeremy Farrar was clearly sort of introducing and ending the meeting. It was his call to make. Neither Fauci or Collins really had much to say, other than just, you know, maybe a point of clarification here or there.

***

Q. …Was Dr. Collins on the call?

A. He was on the call. What I remember was is that he was basically on and off the call, because I think he was having some kind of a social event at the time. So, he did come on and off. But he, you know, he made his presence, you know, just I'm here, basically, known a couple of times.

Q. Was that - - to your recollection, was that the substance of his speaking role?

A. He really didn't offer anything scientifically.[89]

Dr. Kristian Andersen (June 16, 2023)

Q. On the conference call -- we talked a little bit about it -- what do you recall Dr. Fauci saying, if he said anything?

A. I honestly don't remember Dr. Fauci, Collins -- I believe there might've been other NIH contingents on the call too. They probably had some questions, but I don't recollect that they -- they certainly didn't add anything of substance to the scientific discussion. Again, the discussions were: Jeremy said a few things to sort of set up the call and "here's what we're going to do," but, otherwise, the conversation was just between myself, Eddie Holmes, Andy Rambaut, Christian Drosten, Ron Fouchier in particular, so among the experts present on the call.

Q. Do you recall Dr. Collins saying anything on the conference call?

A. I do not, no.[90]

[89] Garry TI, *supra* note 77, at 132.
[90] Andersen TI, *supra* note 55, at 96.

In a transcribed interview, Dr. Tabak testified he joined the call to discuss the presence of O-linked glycans and that the presence of these glycans does not indicate whether COVID-19 emerged as a natural spillover or via a laboratory related incident.

Dr. Lawrence Tabak (January 5, 2024)

Q. …So kind of just the invitation just kind of fell into your inbox, and you went from there?

A. I had a specific reason for wanting to join the call.

Q. What was that?

A. Because I had one observation that I wanted to share with the group, and I did.

Q. Was it the O-linked glycans?

A. Correct.

***

Q. I appreciate it. I'm not a scientist at all, so, like, anything that I've learned is because I've just been listening to people like you. But the presence of the O-linked glycans themselves does not lean one way or another?

A. I don't think so.

Q. Okay.

A. I think you could argue it either way. I really do.[91]

The February 1 conference call was subsequently summarized in a memo.[92]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[91] Tabak TI, *supra* note 83, at 134- 136.
[92] E-Mail from Lawrence Kerr, Ph.D., Dir., Off. Of Pandemic and Emerging Threats, Off. Of Global Affairs, U.S. Dep't of Health & Human Servs., to REDACTED (Feb. 5, 2020, 1:54 AM).

DRAFT PROPOSAL: WHO-Convened Discussion on Evolutionary Origins of 2019-nCoV

Since the release of the first full genome sequence of 2019-nCoV on January 10, 2020, the global scientific community has been rapidly and diligently analyzing the available sequence information and other data in order to learn more about the origins and properties of this newly emerging virus. Initial analyses have identified phylogenetic linkages to other betacoronaviruses from bats, and we anticipate learning more about the origins of this virus as additional sequences are released and further analyses are performed. However, the combination of the global spotlight on the outbreak, the speed at which the results of these analyses are being released (not all of which have been peer-reviewed), and the creation of rumors by multiple and varied interpretations of the results have fueled rumors and suspicion of potential intentional creation of this new virus. To address responsibly such rumors and more fully understand the potential future risk to human health from this and other coronaviruses of animal origin, we propose that WHO bring together scientific experts that are broadly representative of the global scientific community for the specific purpose of evaluating the evolutionary origins of 2019-nCoV.

On February 1, 2020, U.S. National Institutes of Health Director Francis Collins, U.S. National Institute of Allergy and Infectious Diseases Director Anthony Fauci, and Wellcome Trust Director Jeremy Farrar discussed emerging published analyses on potential evolutionary origins of the virus with several highly esteemed scientists with expertise in evolutionary biology. The group was unanimous in their assessment that the paper by an Indian research group pointing out that there are HIV gene sequences in the 2019-nCoV virus and thus indicating intentional insertion were not credible. However, several in the group noted that the sequences of published isolates of the nCoV included mutations in the virus that have never been seen before in a bat virus. Although there were some who felt such mutations could occur naturally, others felt that they were suggestive of intentional insertion, thus questioning the origin of the virus. Thus, the group agreed that it would be beneficial to gather a larger group of scientific experts broadly representative of the global scientific community convened by WHO to discuss the evolutionary origins of 2019-nCoV and its lessons for future risk assessment and understanding of animal/human coronaviruses.

Participants in the call included:

- Francis Collins, Director of the U.S. National Institutes of Health, U.S.;
- Anthony Fauci, Director of the U.S. National Institute of Allergy and Infectious Diseases, U.S.;
- Jeremy Farrar, Director of the Wellcome Trust;
- Patrick Vallance, U.K. Chief Scientific Adviser and Head of the Government Science and Engineering;
- Kristian Anderson, Director of Infectious Disease Genomics, Scripps Research Translational Institute, CA, U.S.;
- Christian Drosten, Director of Human Virology at the German Center for Infection Research at Charité – Universitätsmedizin, Germany;
- Edward Holmes, Professor of Viral Evolution at University of Sydney;
- Andrew Rambaut, Professor of Molecular Evolution, University of Edinburgh's Institute of Evolutionary Biology, U.K.;
- Ron Fouchier, Deputy Head of Department of Viroscience, Erasmus Medical Center, NL;
- Robert Garry, Professor of Virology, Tulane University School of Medicine, Louisiana, U.S. ;
- Mike Ferguson, Professor of Life Sciences at University of Dundee, U.K.; and
- M.P.G. Koopmans, Head of Department of ViroScience, Erasmus Medical Center, NL.

Both Dr. Andersen and Dr. Garry testified regarding if Dr. Fauci ever directed them to write a paper regarding the origins of COVID-19. Dr. Garry testified, "he never directed that to me."[93] However, Dr. Garry clarified, "I'm not privy to all the communications that Dr. Fauci had with the other authors."[94] Dr. Andersen testified that in addition to Dr. Fauci "suggesting" a paper about a potential lab leak on January 31, 2020, on the February 1 Conference Call, Dr. Fauci "encouraged to, you know, follow the scientific process on this which ultimately ends up in peer-reviewed publications."[95] Dr. Andersen clarified that Dr. Fauci specifically mentioned drafting a peer-reviewed paper on January 31, stating, "he specifically mentioned that if I believed this was a lab leak, I should consider writing a peer-reviewed paper on it."[96]

When Dr. Andersen presented a draft of Proximal Origin to *Nature*, he stated it was "prompted" by Dr. Fauci and later stated the goal of Proximal Origin was to "disprove the lab leak theory."[97]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[93] Garry TI, *supra* note 77, at 133-134.
[94] *Id.*
[95] Andersen TI, *supra* note 55, at 145.
[96] *Id.*
[97] E-Mail from Kristian Andersen, Ph.D., Professor, Scripps Research, to Clare Thomas, Editor, Nature (Feb. 12, 2020, 23:09); E-Mail from Kristian Andersen, Ph.D., Professor, Scripps Research, to Christian Drosten, Ph.D., Deputy Coordinator for Emerging Infections, German Center for Infection Research, *et. al.* (Feb. 8, 2020).

From: Kristian G. Andersen [redacted]
Sent: 12 February 2020 23:09
To: Clare Thomas
Subject: Interest in commentary/hypothesis on SARS-CoV-2 origins?

Dear Clare,

I can only imagine you must be crazy busy at the moment! I wanted to reach out to you to see if there would be interest in receiving a commentary/hypothesis piece on the evolutionary origins of SARS-CoV-2? There has been a lot of speculation, fear mongering, and conspiracies put forward in this space and we thought that bringing some clarity to this discussion might be of interest to Nature.

Prompted by Jeremy Farrah, Tony Fauci, and Francis Collins, Eddie Holmes, Andrew Rambaut, Bob Garry, Ian Lipkin, and myself have been working through much of the (primarily) genetic data to provide agnostic and scientifically informed hypotheses around the origins of the virus. We are not quite finished with the writeup and we still have some loose ends, but I wanted to reach out to you to see if this might potentially be of interest? We see this more as a commentary/hypothesis, as opposed to a more long-form Letter or Article.

Best,
Kristian

Kristian G. Andersen, PhD
Associate Professor, Scripps Research
Director of Infectious Disease Genomics, Scripps Research Translational Institute
Director, Center for Viral Systems Biology

The Scripps Research Institute
10550 North Torrey Pines Road, SGM-300A
Department of Immunology and Microbial Science
La Jolla, CA 92037

p: [redacted]
c:
t:
e:
w:

Assistant: [redacted]

When asked about this e-mail, Dr. Garry testified:

Dr. Robert Garry (June 9, 2023)

Q. Did Dr. Andersen ever express this to you, the feeling that he was prompted by Dr. Farrar, Dr. Fauci, and Dr. Collins?

A. I mean, I think in the -- in the broad sense. Yeah, I'm not quite so sure how to answer that. I mean, you know, this is the first time I'm actually seeing this email, the way he wrote it here. So, I'm a little surprised that he wrote it that way. I probably wouldn't have written it this way. But, you know, I think you're probably going to have to ask Kristian what he thought about, you know, why he put it that

way. Maybe he was, you know -- I don't know. I really shouldn't speculate on that. You probably need to ask him.[98]

When asked about this email, Dr. Andersen confirmed that he was referencing the January 31 phone call with Dr. Fauci.

Dr. Kristian Andersen (June 16, 2023)

Q. What did you mean by "prompted by Jeremy Farrar, Tony Fauci, and Francis Collins"?

A. I mean specifically that -- again, as I've already explained, is that they prompted us to the idea of seriously considering the origin of the virus and to consider producing a paper on that…***And, again, remember my first conversation with Tony Fauci, where he specifically suggests that if I think this came from the lab, I should consider writing a scientific paper on it.***

Q. So that's what the - - the prompt he was referencing - - that first conversation?

A. ***Correct.***[99]

The first draft of a report that would become Proximal Origin was completed by 7:40 p.m. on February 1—only hours after the conference call. While it may not have been the goal of the February 1 Conference Call, a written product of some sort was certainly discussed and contemplated on the February 1 Conference Call.

Dr. Robert Garry (June 9, 2023)

Well, you know, of course, we had the teleconference on February the 1st, 2020. And we had already, you know, had many discussions amongst ourselves, I mean. And by ourselves, I mean Kristian and Eddie and Andrew and I, with other people. So, you know, there were sort of notions and ideas circulating around.

And, you know, the possibility of the paper, we're scientists. We write papers. We communicate. We do, you know, we do science communication. That's the sort of the final stamp on a lot of work that you might do is to write up a paper. So, of course, I think that was in everyone's mind…

[98] Garry TI, *supra* note 77, at 166.
[99] Andersen TI, *supra* note 55, at 170.

> And so, I think by, you know, by that February 1 teleconference, if you want to mark it there, I mean, it didn't take too many days after that.[100]

The Stated Goals of Proximal Origin

First, on February 8, 2020, Dr. Andersen wrote, "[o]ur main work over the past couple of weeks has been focused on trying to disprove any type of lab theory, but we are a crossroad where the scientific evidence isn't conclusive enough to say that we have high confidence in any of the three main theories considered."[101]

> On 8 Feb 2020, at 22:15, Kristian G. Andersen <[redacted]> wrote:
>
> A lot of good discussion here, so I just wanted to add a couple of things for context that I think are important - and why what we're considering is far from "another conspiracy theory", but rather is taking a valid scientific approach to a question that is increasingly being asked by the public, media, scientists, and politicians (e.g., I have been contacted by Science, NYT, and many other news outlets over the last couple of days about this exact question).
>
> To Ron's question, passage of SARS-like CoVs have been ongoing for several years, and more specifically in Wuhan under BSL-2 conditions - see references 12-15 in the document for a few examples. The fact that Wuhan became the epicenter of the ongoing epidemic caused by nCoV is likely an unfortunate coincidence, but it raises questions that would be wrong to dismiss out of hand. Our main work over the last couple of weeks has been focused on trying to *disprove* any type of lab theory, but we are at a crossroad where the scientific evidence isn't conclusive enough to say that we have high confidence in any of the three main theories considered. Like Eddie - and I believe Bob, Andrew, and everybody on this email as well - I am very hopeful that the viruses from pangolins will help provide the missing pieces. For now, giving the lab theory serious consideration has been highly effective at countering many of the circulating conspiracy theories, including HIV recombinants, bioengineering, etc. - here's just one example: https://www.factcheck.org/2020/02/baseless-conspiracy-theories-claim-new-coronavirus-was-bioengineered/.
>
> As to publishing this document in a journal, I am currently not in favor of doing so. I believe that publishing something that is open-ended could backfire at this stage. I think it's important that we try to gather additional evidence - including waiting on the pangolin virus sequences and further scrutinize the furin cleavage site and O-linked glycans - before publishing. That way we can (hopefully) come out with some strong conclusive statements that are based on the best data we have access to. I don't think we are there yet.
>
> Best,
> Kristian

Second, on February 20, 2020, Dr. Andersen—in trying to defend the viability of Proximal Origin—wrote, "[u]nfortunately none of this helps refute a lab origin and the possibility must be considered as a serious scientific theory (which is what we do) and not dismissed out of hand as another 'conspiracy' theory. We all really, really wish that we could do that (that's how this got started), but unfortunately it's just not possible given the data."[102]

---

[100] Garry TI, *supra* note 77, at 130-131.
[101] E-Mail from Kristian Andersen, Ph.D., Professor, Scripps Research, to Christian Drosten, Ph.D., Deputy Coordinator for Emerging Infections, German Center for Infection Research, *et. al.* (Feb. 8, 2020, 22:15).
[102] E-Mail from Kristian Andersen, Ph.D., Professor, Scripps Research, to Clare Thomas, Ph.D., Senior Editor, Nature (Feb. 20, 2020, 17:48).

From: Kristian G. Andersen [redacted]
Sent: 20 February 2020 17:48
To: Clare Thomas
Subject: Re: Decision on Nature submission 2020-02-02583

Thanks Clare for letting me know so quickly. I'll discuss with the other authors to see what the best path would be - just one thing to make clear though, reviewer 2 is unfortunately wrong about "Once the authors publish their new pangolin sequences, a lab origin will be extremely unlikely". Had that been the case, we would of course have included that - but the more sequences we see from pangolins (and we have been analyzing/discussing these *very* carefully) the more unlikely it seems that they're intermediate hosts. They definitely harbor SARS-CoV-like viruses, no doubt, but it's unlikely they have a direct connection to the COVID-19 epidemic. Unfortunately none of this helps refute a lab origin and the possibility must be considered as a serious scientific theory (which is what we do) and not dismissed out of hand as another 'conspiracy' theory. We all really, really wish that we could do that (that's how this got started), but unfortunately it's just not possible given the data.

Thanks again for considering our manuscript and while we had of course hoped for a better outcome, we understand the decision.

Best,
Kristian

According to Dr. Farrar, in addition to the specific goal of disproving the lab leak theory, Proximal Origin was to be a "go to scientific statement to refer to."[103] Further, Dr. Farrar e-mailed Dr. Daszak and stated the goal of Proximal Origin was to "effectively [put] to bed the issue of the origin of the virus."[104]

From: Jeremy Farrar <[redacted]
To: "Peter Daszak" [redacted] "Christian Drosten" [redacted] "Michael RYAN" <[redacted] "Bernhard F. SCHWARTLANDER" [redacted]
Subject: COVID-19 issue
Sent: Wed 2/12/2020 9:34:49 AM (UTC-05:00)

Got a taxi to airport and on flight with Peter.

I hope there is a paper/letter ready this week to go to Nature (and WHO) which effectively puts to bed the issue of the origin of the virus.

I do think important to get ahead of even more discussion on this which may well come if this spreads more to US and elsewhere and other "respected" scientists publish something more inflammatory.

[103] E-Mail from Jeremy Farrar, Ph.D., Dir., Wellcome Trust, to Kristian Andersen, Ph.D., Professor, Scripps Research, *et. al.* (Feb. 8, 2020).
[104] E-Mail from Jeremy Farrar, Ph.D., Dir., Wellcome Trust, to Peter Daszak, Ph.D., Pres., EcoHealth Alliance, Inc. (Feb. 12, 2020, 9:34 AM).

The Possible Motives of Proximal Origin

The first possible motive to downplay the lab leak theory was an interest by those involved to defend China. This motive was expressed by numerous individuals including Dr. Farrar, Dr. Rambaut, Dr. Andersen, Dr. Fouchier. Similarly, Dr. Collins expressed concerns regarding "international harmony."[105]

1. Dr. Andrew Rambaut

On February 2, 2020, Dr. Rambaut, communicating over a private Slack channel with Dr. Andersen, Dr. Holmes, and Dr. Garry, wrote, "given the shit show that would happen if anyone serious accused the Chinese of even accidental release, my feeling is we should say that given there is no evidence of a specifically engineered virus, we cannot possibly distinguish between natural evolution and escape so we are content with ascribing it to natural process."[106]

2. Dr. Kristian Andersen

In response to Dr. Rambaut's message above, Dr. Andersen replied, "[y]up, I totally agree that that's a very reasonable conclusion. Although I hate when politics is injected into science – but its impossible not to, especially given the circumstances."[107]

3. Dr. Ron Fouchier

Dr. Fouchier, in emails following the February 1 Conference Call, stated, "…further debate about such accusations would unnecessarily distract top researchers from their active duties and do unnecessary harm to science in general and science in China in particular."[108]

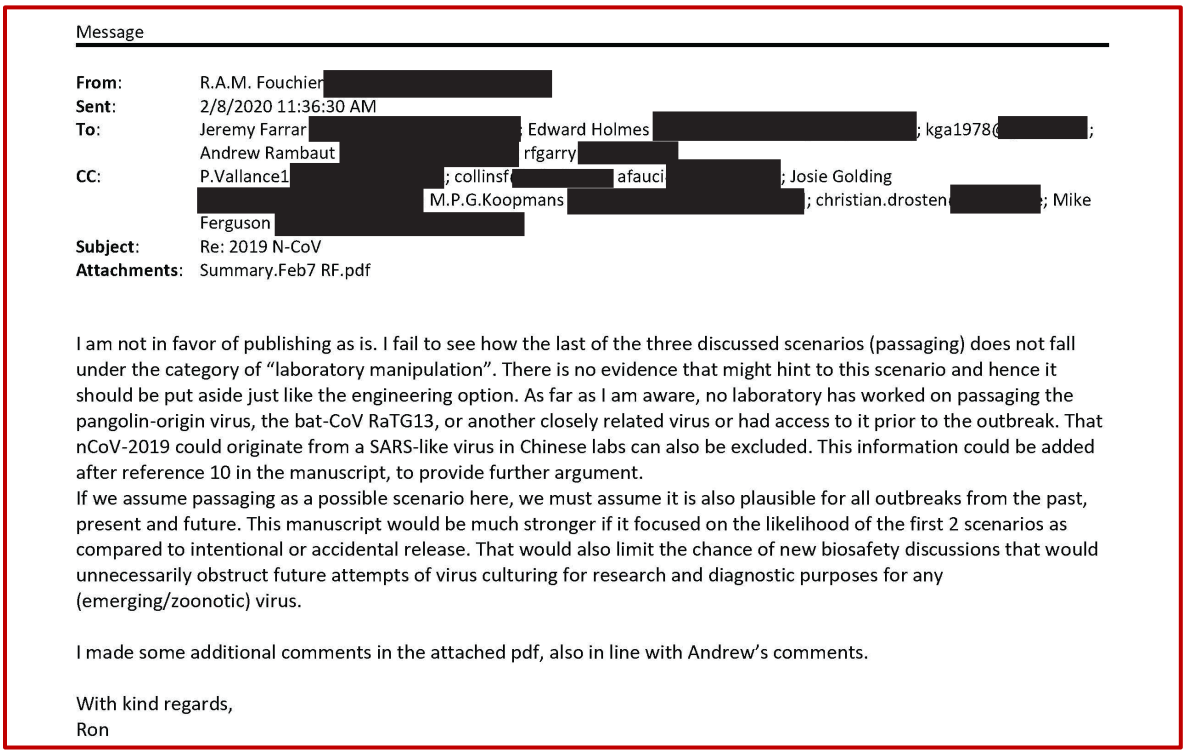
4. Dr. Francis Collins

Dr. Collins, in emails following the February 1 Conference Call, stated, "…the voices of conspiracy will quickly dominate, doing great potential harm to science and international harmony."[109]

The second possible motive to downplay the lab leak theory was to lessen the likelihood of increased biosafety and laboratory regulations. Dr. Fouchier stated, "[t]his manuscript would be much stronger if it focused on the likelihood of the first 2 scenarios as compared to intentional or accidental release. That would also limit the chance of new biosafety discussion that would

[105] E-Mail from Francis Collins, M.D., Dir. Nat'l Insts. of Health, to Jeremy Farrar, M.D., Dir. Wellcome Trust, *et. al.* (Feb. 2, 2020).
[106] Message from Andrew Rambaut, Ph.D., Slack (Feb. 2, 2020, 11:53 AM).
[107] Message from Kristian Andersen, Ph.D., Slack (Feb. 2, 2020, 11:56 AM).
[108] E-Mail from Ron Fouchier, Ph.D., Deputy Head of the Erasmus MC Department of Viroscience, Erasmus MC, to Jeremy Farrar, Ph.D., Dir. Wellcome Trust, *et. al.* (Feb. 2, 2020, 8:30 AM).
[109] E-Mail from Francis Collins, M.D., Ph.D., Dir. Nat'l Insts. of Health, to Jeremy Farrar, Ph.D., Dir. Wellcome Trust, *et al.* (Feb. 2, 2020, 10: 27).

unnecessarily obstruct future attempts of virus culturing for research and diagnostic purposes for any (emerging/zoonotic virus).”[110]



Message

From: R.A.M. Fouchier
Sent: 2/8/2020 11:36:30 AM
To: Jeremy Farrar; Edward Holmes; kga1978; Andrew Rambaut; rfgarry
CC: P.Vallance1; collinsf; afauci; Josie Golding; M.P.G.Koopmans; christian.drosten; Mike Ferguson
Subject: Re: 2019 N-CoV
Attachments: Summary.Feb7 RF.pdf

I am not in favor of publishing as is. I fail to see how the last of the three discussed scenarios (passaging) does not fall under the category of “laboratory manipulation”. There is no evidence that might hint to this scenario and hence it should be put aside just like the engineering option. As far as I am aware, no laboratory has worked on passaging the pangolin-origin virus, the bat-CoV RaTG13, or another closely related virus or had access to it prior to the outbreak. That nCoV-2019 could originate from a SARS-like virus in Chinese labs can also be excluded. This information could be added after reference 10 in the manuscript, to provide further argument.
If we assume passaging as a possible scenario here, we must assume it is also plausible for all outbreaks from the past, present and future. This manuscript would be much stronger if it focused on the likelihood of the first 2 scenarios as compared to intentional or accidental release. That would also limit the chance of new biosafety discussions that would unnecessarily obstruct future attempts of virus culturing for research and diagnostic purposes for any (emerging/zoonotic) virus.

I made some additional comments in the attached pdf, also in line with Andrew’s comments.

With kind regards,
Ron

The Involvement of Dr. Fauci, Dr. Collins, and Dr. Farrar

Throughout the drafting process, the authors of Proximal Origin were keenly aware of the influence of Dr. Fauci, Dr. Collins, and Dr. Farrar.

It appears a draft of Proximal Origin did not leave the authorship group until on or around February 4 or 5. Dr. Andersen wrote to Dr. Holmes, Dr. Garry, and Dr. Rambaut, “[u]nless others have further comments, I’d say this is ready to go up the chain.”[111] Dr. Holmes responded, “[w]orks for me. Should I quickly check with Jeremy to see if he is happy for it to be circulated to the higher group?”[112] A few hours later, Dr. Holmes sent the first summary to Dr. Farrar.[113]

[110] E-Mail from Ron Fouchier, Ph.D., Deputy Head of the Erasmus MC Department of Viroscience, Erasmus MC, to Jeremy Farrar, Ph.D., Dir. Wellcome Trust, *et. al.* (Feb. 8, 2020, 11:36 AM).
[111] E-Mail from Kristian Andersen, Ph.D., Professor Scripps Research, to Robert Garry, Ph.D., Professor, Tulane School of Medicine, *et. al.* (Feb. 5, 2020).
[112] E-Mail from Dr. Edward Holmes, Ph.D., Professor, University of Sydney, to Kristian Andersen, Ph.D., *et. al.,* Professor Scripps Research (Feb. 4, 2020).
[113] E-Mail from Dr. Edward Holmes, Ph.D., Professor, University of Sydney, to Robert Garry, Ph.D., *et. al.,* Professor, Tulane School of Medicine (Feb. 4, 2020, 12:36 PM).

On Tue, Feb 4, 2020 at 12:36 PM Edward Holmes <[redacted]> wrote:

I've just passed to Jeremy.

PROFESSOR EDWARD C. HOLMES FAA FRS
ARC Australian Laureate Fellow

THE UNIVERSITY OF SYDNEY
Marie Bashir Institute for Infectious Diseases & Biosecurity,
School of Life & Environmental Sciences and School of Medical Sciences,
The University of Sydney | Sydney | NSW | 2006 | Australia
T
E [redacted]

Dr. Farrar immediately sent the draft to Dr. Fauci and Dr. Collins.[114]

From: Jeremy Farrar (b) (6)
Sent: Tuesday, February 4, 2020 2:01 AM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Collins, Francis (NIH/OD) [E] (b) (6)>
Subject: FW: Prevalence of infection and stage of the epidemic in Wuhan

Please treat in confidence – a very rough first draft from Eddie and team – they will send on the edited, cleaner version later.

Pushing WHO again today

In response to the draft, Dr. Collins wrote, "…repeated tissue culture passage is still an option – though it doesn't explain the O-linked glycans" and "I'd be interested in the proposal of accidental lab passage in animals (which ones?)." Dr. Fauci responded, "?? Serial passage in ACE2-transgenic mice."

After Dr. Farrar received their responses, he recounted them to Dr. Holmes.[115]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[114] E-Mail from Jeremy Farrar, Ph.D., Dir. Wellcome Trust, to Anthony Fauci, Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, & Francis Collins, M.D., Ph.D., Dir., Nat'l Insts. of Health (Feb. 4, 2020, 2:01 AM).
[115] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Robert Garry, Ph.D., Professor, Tulane School of Medicine, *et. al*. (Feb. 4, 2020, 2:59 PM).

On Tue, Feb 4, 2020 at 2:59 PM Edward Holmes [redacted] wrote:

Agreed. Timing is perfect.

Bob - a question from Jeremy:

"Quick question though - why could passage in animals in lab work add the glycans?"

Any thoughts?

Eddie

PROFESSOR EDWARD C. HOLMES FAA FRS
ARC Australian Laureate Fellow

THE UNIVERSITY OF SYDNEY
Marie Bashir Institute for Infectious Diseases & Biosecurity,
School of Life & Environmental Sciences and School of Medical Sciences,
The University of Sydney | Sydney | NSW | 2006 | Australia
T
E [redacted]

Around this time, the authors were awaiting new sequences, Dr. Holmes stated, "[s]hould I tell Jeremy to hold sending the summary out to the group while we investigate more or does that really matter? He did say that more wildlife needed to be studied. He's sent it to the Bethesda Boys."[116] Dr. Rambaut responded, "[p]erhaps we say we are adding new information? See whether he wants to hold off. I suspect Bethesda will be sending it round already?"[117] These are apparent references to Dr. Fauci and Dr. Collins.

Dr. Robert Garry (June 9, 2023)

Q. Who do you think the "Bethesda Boys" are?

A. I'm not 100 percent sure, but I think I can make an educated guess that this was Dr. Fauci and Dr. Collins.

Q. Is it your estimation that "Bethesda" also refers to Dr. Fauci and Dr. Collins?

A. Yes.[118]

Dr. Kristian Andersen (June 16, 2023)

Q. Who is Dr. Holmes referencing when he says, "Bethesda Boys"?

A. I don't know, but I assume he means the NIH folks and -- them, so that would be my best guess, yeah.

[116] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Andrew Rambaut, Ph.D., Professor, University of Edinburgh, *et. al.* (Feb. 5, 2020).
[117] E-Mail from Andrew Rambaut, Ph.D., Professor, University of Edinburgh, to Edward Holmes, Ph.D., Professor, University of Sydney, *et. al.* (Feb. 5, 2020).
[118] Garry TI, *supra* note 77, at 174.

Q. Is it your same presumption that he's referencing NIH?

A. That's my assumption, yes.[119]

On February 7, 2020, Dr. Farrar said, "will share with TC [teleconference] group over the weekend…"[120] On February 8, Dr. Farrar forwarded a draft of Proximal Origin to the same participants of the February 1 Conference Call—further linking that call to the conception of Proximal Origin.[121]

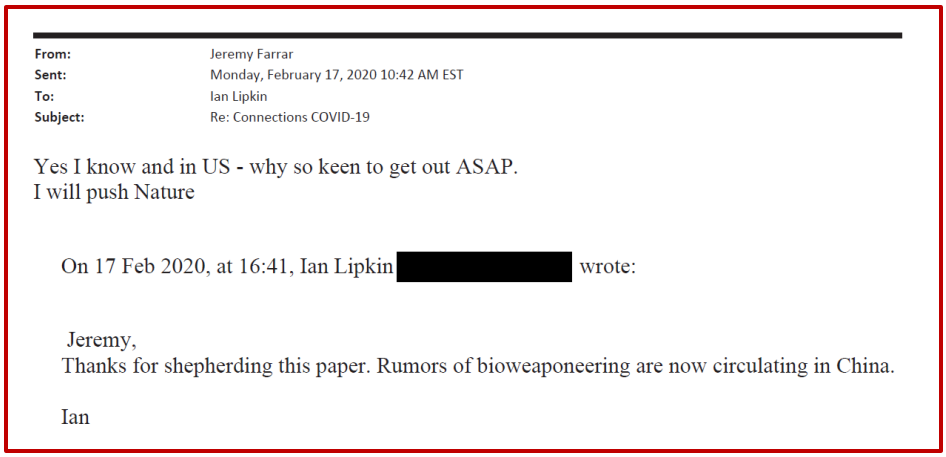
Within hours of receiving the draft, Dr. Fauci, worried about the possibility of serial passage in animals in a lab, asked the whole group, "[w]ould serial passage in an animal in the laboratory give the same result as prolonged adaption in animals in the wild? Or is there something that is fundamentally different in what happens when you serial passage versus natural animal adaption?"[122] Dr. Garry responded, "[i]t's possible to fairly rapidly select for more pathogenic variants in the laboratory."[123]

In addition to Dr. Fauci's and Dr. Collin's involvement, Dr. Farrar led the drafting process and made at least one direct edit to Proximal Origin. Dr. Farrar, however, is not credited as having any involvement in the drafting and publication of Proximal Origin, when in fact he led the drafting process and made direct substantive edits to the publication.

On February 17, 2020, right before publication, Dr. Lipkin emailed Dr. Farrar to thank him for leading the drafting process of Proximal Origin, to which Dr. Farrar responded that he will "push" the publisher.[124]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[119] Andersen TI, *supra* note 55, at 176.
[120] E-Mail from Jeremy Farrar, Ph.D., Dir. Wellcome Trust, to Edward Holmes, Ph.D., Professor, University of Sydney, *et. al* (Feb. 7, 2020).
[121] E-Mail from Jeremy Farrar, Ph.D., Dir. Wellcome Trust, to Edward Holmes, Ph.D., Professor, University of Sydney, *et. al* (Feb. 8, 2020).
[122] E-Mail from Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Jeremy Farrar, Ph.D., Dir., Wellcome Trust , *et. al* (Feb. 8, 2020).
[123] E-Mail from Robert Garry, Ph.D., Professor, Tulane College of Medicine, to Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health , *et. al* (Feb. 8, 2020).
[124] E-Mail from Ian Lipkin, M.D., Professor, Columbia University, to Jeremy Farrar, Ph.D., Dir. Wellcome Trust (Feb. 17, 2020).



From: Jeremy Farrar
Sent: Monday, February 17, 2020 10:42 AM EST
To: Ian Lipkin
Subject: Re: Connections COVID-19

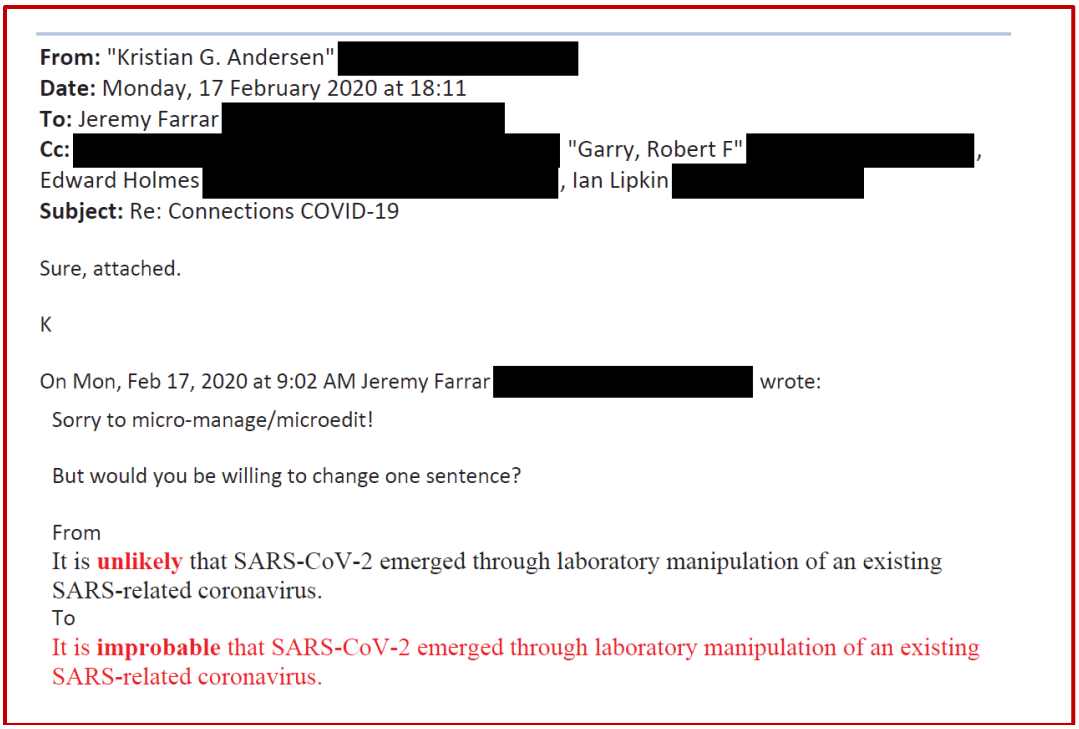
Yes I know and in US - why so keen to get out ASAP.
I will push Nature

On 17 Feb 2020, at 16:41, Ian Lipkin [redacted] wrote:

Jeremy,
Thanks for shepherding this paper. Rumors of bioweaponeering are now circulating in China.

Ian

Further, Dr. Andersen testified that Dr. Farrar was the "father figure" of Proximal Origin.[125] In addition to leading the drafting and publication process, Dr. Farrar made at least one direct edit to Proximal Origin.[126]



From: "Kristian G. Andersen" [redacted]
Date: Monday, 17 February 2020 at 18:11
To: Jeremy Farrar [redacted]
Cc: [redacted] "Garry, Robert F" [redacted], Edward Holmes [redacted], Ian Lipkin [redacted]
Subject: Re: Connections COVID-19

Sure, attached.

K

On Mon, Feb 17, 2020 at 9:02 AM Jeremy Farrar [redacted] wrote:

Sorry to micro-manage/microedit!

But would you be willing to change one sentence?

From
It is **unlikely** that SARS-CoV-2 emerged through laboratory manipulation of an existing SARS-related coronavirus.
To
It is **improbable** that SARS-CoV-2 emerged through laboratory manipulation of an existing SARS-related coronavirus.

This evidence suggests that Dr. Farrar was involved in the drafting and publication of Proximal Origin and probably should have been credited or acknowledged for this involvement. Both Dr. Fauci and Dr. Collins testified they did not provide edits to Proximal Origin.

[125] Andersen TI, *supra* note 55, at 180.
[126] E-Mail from Jeremy Farrar, Ph.D., Dir., Wellcome Trust, to Kristian Andersen, Ph.D., Professor, Scripps Research, et al. (Feb. 17, 2020, 10: 42 AM).

The Involvement of Dr. Lipkin

Dr Lipkin was the only author of Proximal Origin that was not on the February 1 Conference Call.[127] Dr. Lipkin confirmed he was not even invited to the February 1 Conference Call, and he had no prior knowledge of the call taking place.[128]

> **Dr. Ian Lipkin (April 6, 2023)**
>
> Q. When did you eventually learn of the call?
>
> A. Actually, I learned of it far more recently than you might expect - - I can't tell you precisely when, but I did not know about it in February of 2020.
>
> Q. The existence of the call or what was communicated on the call was not communicated to you during the drafting or Proximal Origin?
>
> A. That is correct.[129]

Despite the authors completing the first draft of Proximal Origin by February 1, Dr. Lipkin was not invited to join and was not sent a draft until February 10.[130] In that email, Dr. Holmes stated, "I'll have to chat with Jeremy in a little while to see if I can get you more directly involved."[131] It is unclear, why Dr. Farrar had approval over Dr. Lipkin's involvement.

Prior to being added as an author, Dr. Lipkin spoke to Dr. Holmes a few times. On at least one occasion, Dr. Lipkin raised concerns regarding the furin cleavage site. As Dr. Holmes recounted on February 10, "Ian Lipkin just called – very worried about the furin cleavage site and says that high ups are as well, inc. intel."[132] Dr. Holmes later said, "I think Ian thinks it's from a lab."[133]

After reading the draft shared with him, Dr. Lipkin responded:[134]

---

[127] Lipkin TI, *supra* note 38, at 92.
[128] *Id*.
[129] *Id.*
[130] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Ian Lipkin, M.D., Professor, Columbia University (Feb. 10, 2023).
[131] *Id.*
[132] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Andrew Rambaut, Ph.D., Professor, University of Edinburgh, *et. al.* (Feb. 10, 2020).
[133] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Kristian Andersen, Ph.D., Professor Scripps Research, *et. al.* (Feb. 11, 2020).
[134] E-Mail from Ian Lipkin, M.D., Professor, Columbia University, to Eddie Holmes, Ph.D., Professor, University of Sydney (Feb. 11, 2020, 9:01 AM).

On 11 Feb 2020, at 9:01 am, Ian Lipkin [redacted] wrote:

It's well reasoned and provides a plausible argument against genetic engineering. It does not eliminate the possibility of inadvertent release following adaptation through selection in culture at the institute in Wuhan. Given the scale of the bat CoV research pursued there and the site of emergence of the first human cases we have a nightmare of circumstantial evidence to assess.

Ian

Dr. Garry testified that Dr. Lipkin "…made a nice authorship contribution" and that "he read the paper many times and made some good comments back and forth…"[135] Dr. Lipkin testified that he believed he was added to Proximal Origin because of his prior authorship of related papers.

Dr. Ian Lipkin (April 6, 2023)

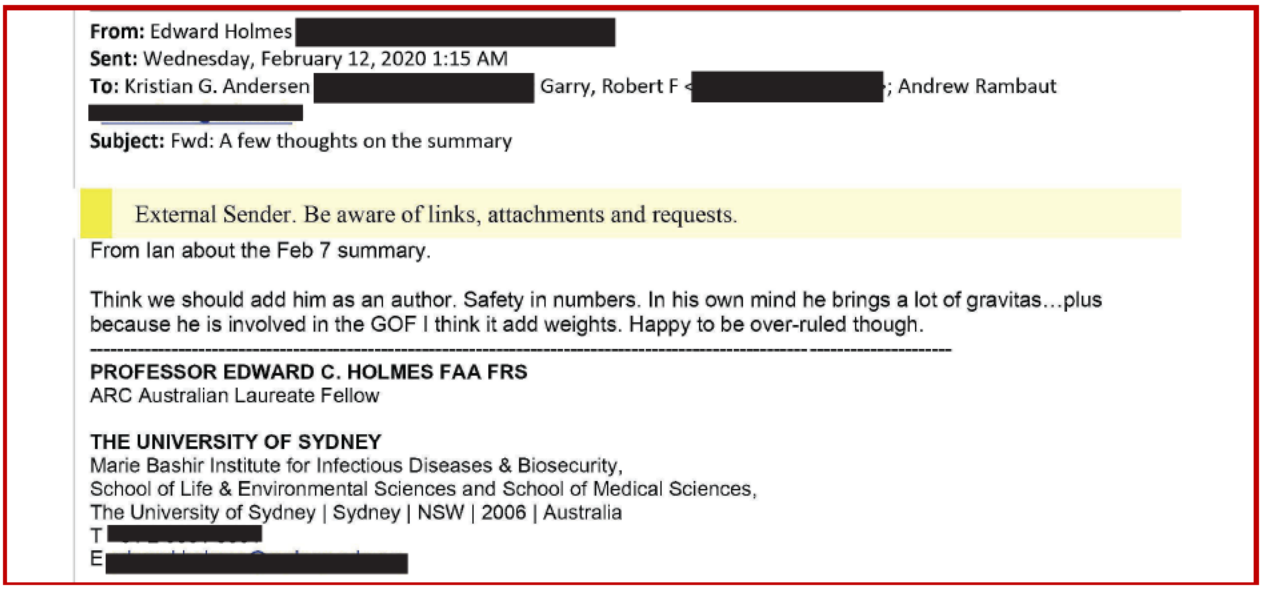
Q. Why do you think Dr. Holmes invited you to join as an author?

A. I had written an article on why the risk of wild animal markets. I sent it to him, asked him to be a coauthor with me. He agreed. And my guess is that it was in that context that he invited me to join this paper.[136]

However, this is not what the other authors discussed when considering whether to add him to the authorship group. According to Dr. Holmes, the authors added Dr. Lipkin as an author not necessarily for his expertise but for "safety in numbers" and "gravitas."[137]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[135] Garry TI, *supra* note 77, at 160.
[136] Lipkin TI, *supra* note 38, at 93.
[137] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Kristian Andersen, Ph.D., Professor, Scripps Research, *et. al.* (Feb. 12, 2020, 1:15 AM).



From: Edward Holmes [redacted]
Sent: Wednesday, February 12, 2020 1:15 AM
To: Kristian G. Andersen [redacted] Garry, Robert F [redacted]; Andrew Rambaut [redacted]
Subject: Fwd: A few thoughts on the summary

External Sender. Be aware of links, attachments and requests.

From Ian about the Feb 7 summary.

Think we should add him as an author. Safety in numbers. In his own mind he brings a lot of gravitas…plus because he is involved in the GOF I think it add weights. Happy to be over-ruled though.

PROFESSOR EDWARD C. HOLMES FAA FRS
ARC Australian Laureate Fellow

THE UNIVERSITY OF SYDNEY
Marie Bashir Institute for Infectious Diseases & Biosecurity,
School of Life & Environmental Sciences and School of Medical Sciences,
The University of Sydney | Sydney | NSW | 2006 | Australia
T [redacted]
E [redacted]

Dr. Garry testified that he agreed with Dr. Holmes, stating, "I mean, I think I must have agreed generally about it because I did concur with adding him as an author. I'm not sure I agree with every rationale there. I'm not sure that the GOF really adds much weight."[138]

Dr. Andersen testified that he agreed with Dr. Holmes, stating, "I think he is an -- you know, he has done important work and including collaborated with Chinese authors. He's a well-known individual within sort of the emerging infectious disease field. So, from that perspective, adding Ian as an author, yes, that helps add to the weight of the paper and the authors, and, like, look, these are really experts to have looked at this, yes."[139]

Proximal Origin's Flawed Scientific Analysis

The conclusions of Proximal Origin rested on three main arguments: (1) the presence of a non-optimal RBD and that RBD appearing in other viral sequences—particularly pangolins, (2) the presence or furin cleavage sites in other coronaviruses, and (3) the concept that any laboratory manipulation would have used an already published viral backbone.[140] Each of these arguments was flawed and rested on unsupported assumptions.

1. The Receptor Binding Domain

"While the analyses above suggest that SARS-CoV-2 may bind human ACE2 with high affinity, computational analyses predict that the interaction is not ideal and that the RBD sequence is different from those shown in SARS-CoV to be optimal for receptor binding. Thus, the high-affinity binding of the SARS-CoV-2 spike protein to human ACE2 is most likely the result of natural selection on a human or human-like ACE2 that permits another optimal binding solution

[138] Garry TI, *supra* note 77, at 161.
[139] Andersen TI, *supra* note 55, at 163-164.
[140] Proximal Origin, *supra* note 42.

to arise. This is strong evidence that SARS-CoV-2 is not the product of purposeful manipulation."[141]

As discussed in a May 26, 2020 Working Paper authored independently by DIA scientists entitled, "Critical analysis of *Andersen et al. The proximal origin of SARS-CoV-2"* [hereinafter "Working Paper"], this argument rested on assumptions rather than facts.[142] Instead of relying on scientific data or evidence, Proximal Origin assumes a methodology and intent of a fictional scientist.[143] In essence, Proximal Origin argues that this fictional scientist would want to design the most optimal RBD possible, which COVID-19 does not possess.

Dr. Kristian Andersen (June 16, 2023)

We knew, based on, you know, much of the great research that Dr. Baric did with SARS-1 is that based on that were predictions of here's the optimal way in which a sarbecovirus will bind into the human ACE2 receptor. That is described in the literature, right? So, if you were to design a new receptor binding domain, presumably you would choose that, right? That would be the logical way to do it.

And SARS-2 doesn't have that at all. It has a completely different solution, right, which we had never seen before. Yet it still appeared to bind well to the human ACE2 receptor -- which we now know, yes, it does bind well to the human ACE2 receptor, but it binds well to a lot of other ACE2 receptors, right, not just human.

So, yeah, that's the idea behind, like, if you were to build this from scratch, you would take the solution that you already know works well. Because that's how science is done, molecular biology is being done.[144]

The Working Paper outlined that a more common approach is to simulate nature in the lab by taking novel coronaviruses and simulating recombination events—even by inserting furin cleavage sites—instead of optimizing the virus.[145] This was explained further during a transcribed interview with an author of the Working Paper, CDR Chretien.

CDR Jean-Paul Chretien (June 29, 2023)

A. Well, they had pointed out that the receptor-binding domain would not have been predicted to be very good or optimal for infecting human cells. And for me that implied an assumption that if

[141] Proximal Origin, *supra* note 42.
[142] CDR Jean-Paul Chretien & Dr. Greg Cutlip, *Working Paper 26 May 2020: Critical Analysis of Andersen et. al. The proximal origin of SARS-Cov-2,* DEF. INTEL. AGENCY (May 26, 2020) [hereinafter "Chretien & Cutlip Working Paper"].
[143] *Id.*
[144] Andersen TI, *supra* note 55, at 122.
[145] Chretien & Cutlip Working Paper, *supra* note 142.

SARS-CoV-2, whatever was in lab, that it probably would have come about in that way where one might have a priori designed a sequence to infect human cells. And that certainly is possible, but we showed examples of the literature of novel coronaviruses being developed in different ways, and what we -- what we found was more of an empirical approach where one might take a backbone virus, a coronavirus from one species and insert part of a coronavirus from another species to observe the effects, and all serving stated purposes of developing medical countermeasures or improving public health. But what we saw in scientific practice was much more of an empirical approach and not -- not an approach by design to achieve a specific function.

Q. So, the reality was scientists more taking an approach to try to mimic natural recombination to see what those viruses would do in a human population?

A. Yes.

Q. Not with a stated goal of making the most effective coronavirus possible?

A. That's right.[146]

When asked if the arguments in Proximal Origin regarding the RBD rested on assumptions, Dr. Garry testified:

Dr. Robert Garry (June 9, 2023)

Q. Is that still resting on an assumption that that's not done, that they weren't testing suboptimal RBDs at some point?

A. I suppose, but why would you do that, you know? I mean, especially if you're thinking that this virus was somehow engineered to be a weapon or, you know, at least be a good pathogen, you wouldn't make a binding domain that was, you know, as poor as your computer predicted it would be for either one of those scenarios.[147]

"The finding of SARS-CoV-like coronaviruses from pangolins with nearly identical RBDs, however, provides a much stronger and more parsimonious explanation of how SARS-CoV-2 acquired these via recombination or mutation."[148]

[146] Transcribed Interview of CDR Jean-Paul Chretien, Program Manager, Biological Technologies Office, Defense Advanced Research Projects Agency, at 35 (June 29, 2023) [hereinafter "Chretien TI"].
[147] Garry TI, *supra* note 77, at 151.
[148] Proximal Origin, *supra* note 42.

Again, according to CDR Chretien, the discovery of a very similar RBD in a naturally occurring pangolin virus is largely irrelevant.

CDR Jean-Paul Chretien (June 29, 2023)

So one of the -- the scenarios we laid out as plausible, and I think would still be plausible, is to begin with a bat origin coronavirus, something along the lines of RaTG13 but more similar to the -- or very, very closely similar to SARS-CoV-2, and then -- and then evaluate the effects of inserting a receptor-binding domain from another species, such as a pangolin. And that's consistent with work that we've seen published from various coronavirus research labs and would be consistent with the observed SARS-CoV-2 as well.[149]

Dr. Garry agreed that this scenario was an entirely plausible outcome.

Dr. Robert Garry (June 9, 2023)

Q. If I in theory were to take that particular pangolin spike protein and attach it to a backbone of some other virus, that product that I would have created, though, theoretically in a lab, would itself have had the six key amino acid mutations being discussed here, right? I know that's a - - hypothetical question.

A. The way you said it, hypothetically, sure.[150]

Further, Dr. Garry testified that the pangolin sequences "are interesting, but they, you know, by themselves, don't tell you that, the virus was natural or from a lab."[151]

Dr. Robert Garry (June 9, 2023)

Q. What does this mean?

A. Okay. It means that, you know, the pangolin sequences are interesting, but they, you know, by themselves, don't tell you that, the virus was natural or from a lab…You know, the pangolin viruses, by themselves you know, they have the similarity in the receptor binding domain, but, you know, there are other viruses out there like RaTG13 that is still, you know, a closer virus overall. None of the viruses that were known have a furin cleavage site, at least in these, you know, these close -- the ones that we're talking about here.[152]

[149] Chretien TI, *supra* note 146, at 36.
[150] Garry TI, *supra* note 77, at 112.
[151] *Id.*
[152] *Id.*

When asked if Proximal Origin's arguments regarding the RBD ruled out a lab origin, CDR Chretien testified, "[n]ot in my assessment."[153] It is clear, the science and facts did not support Proximal Origin's conclusion that COVID-19's RBD "is strong evidence that SARS-CoV-2 is not the product of purposeful manipulation."[154]

2. The Furin Cleavage Site

"Polybasic cleavage sites have not been observed in related 'lineage B' betacoronaviruses, although other human betacoronaviruses, including HKU1 (lineage A), have those sites and predicted O-linked glycans. Given the level of genetic variation in the spike, it is likely that SARS-CoV-2-like viruses with partial or full polybasic cleavage sites will be discovered in other species."[155]

The central pillar of Proximal Origin's argument is that science would eventually find a furin cleavage site in a related coronavirus. This is a clear assumption with no proof nor evidence. Further, as of December 4, 2024, there still has not been a furin cleavage site discovered in sarbecoviruses—the subgenus COVID-19 belongs to—despite years of searching.

Dr. Andersen confirmed the rarity of furin cleavage sites in sarbecoviruses, stating, "…the furin cleavage site itself, which we had not seen in sarbecoviruses before."[156] Dr. Garry confirmed this, stating, "…SARS-Cov-2 so far is the only sarbecovirus that has a furin cleavage site."[157] Further, Dr. Lipkin stated, "[s]o, amongst the SARS-like viruses, and there are many coronaviruses, that was the first time that we'd seen that furin cleavage type."[158] When asked, "[h]ave there been any other SARS-related viruses…that has had a furin cleavage site?," Dr. Farzan testified, "[n]o."[159] Finally, when asked, "…has there been a furin site observed in any viruses in the sarbecovirus family other than COVID-19?," CDR Chretien stated, "…not to my knowledge."[160]

"The acquisition of both the polybasic cleavage site and predicted O-linked glycans also argues against culture-based scenarios. New polybasic cleavage sites have been observed only after prolonged passage of low-pathogenicity avian influenza virus in vitro or in vivo. Furthermore, a hypothetical generation of SARS-CoV-2 by cell culture or animal passage would have required prior isolation of a progenitor virus with very high genetic similarity, which has not been described. Subsequent generation of a polybasic cleavage site would have then required repeated passage in cell culture or animals with ACE2 receptors similar to those of humans, but such work has also not previously been described. Finally, the generation of the predicted O-linked

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[153] Chretien TI, *supra* note 146, at 36.
[154] Proximal Origin, *supra* note 42.
[155] *Id.*
[156] Andersen TI, *supra* note 55, at 95.
[157] Garry TI, *supra* note 77, at 119.
[158] Lipkin TI, *supra* note 38, at 70.
[159] Transcribed Interview of Michael Farzan, Ph.D., Professor of Pediatrics, Harvard Medical School (Apr. 21, 2023) [hereinafter "Farzan TI"].
[160] Chretien TI, *supra* note 146, at 37.

glycans is also unlikely to have occurred due to cell-culture passage, as such features suggest the involvement of an immune system."

Again, according to the Working Paper, this argument rested on a false assumption that all research is published. Dr. Garry testified:

> **Dr. Robert Garry (June 9, 2023)**
>
> Q. Is it possible - - maybe not probable, but possible - - that scientists do experiments they don't publish?
>
> A. Sure.[161]

Dr. Lipkin testified:

> **Dr. Ian Lipkin (April 6, 2023)**
>
> Q. Do you know of any researchers that don't publish everything they sequence?
>
> A. Yes.[162]

Dr. Farzan testified:

> **Dr. Michael Farzan (April 21, 2023)**
>
> Q. …have you ever conducted or known someone to conduct an experiment that they did not publish or make public?
>
> A. Sure.[163]

Further, many involved in Proximal Origin, or the February 1 Conference Call believe that it is possible to manipulate a novel coronavirus in a lab to force the selection of a furin cleavage site. In an email, Dr. Garry wrote, "[b]ottom line – I think that if you put selection pressure on a Cov without a furin cleavage site in cell culture you could well generate a furin cleavage site after a number of passages…"[164]

[161] Garry TI, *supra* note 77, at 153.
[162] Lipkin TI, *supra* note 38, at 70.
[163] Farzan TI, *supra* note 159, at 26.
[164] E-Mail from Robert Garry, Ph.D., Professor, Tulane School of Medicine, to Kristian Andersen, Ph.D., Professor, Scripps Research, *et. al.* (Feb. 4, 2020, 2:50 PM).

From: Robert Garry [redacted]
Date: Tuesday, February 4, 2020 at 5:56 PM
To: Kristian Andersen [redacted], Edward Holmes [redacted]
Cc: "rambaut [redacted]
Subject: Re: Summary - Invitation to edit

Kristian that's correct about everything he said for the P residue. It's what's shifted me to thinking that the insert of the furin site is the result of cell culture passage [or less likely intense transmission in a nonbat host]. Really need to see the data from Ron about generating the furim cleavage site on in vitro passage. Really!

CoV come with or without a furin site. CoV without a furin site are said to be non-cleaved and rely on endosomal proteases like cathepsin for entry. However if you infect a virus like SARS in culture in the presense of exogenous protease like trypsin its 100X more effective at entering because the spike gets cleaved and it can enter at the cell surface.

You have to infect flu viruses (the ones without the multibasic cleavage site) in the presence of trypsin, and include trypsin in the overlay if you want to get virus spread aka plaques.

This also contributes to the pathogenicity of - well - highly pathogenic flu virus – different tissues have different proteases and are able to "activate" flu to different extents - if the flu v has a furin cleavage site it has a lot more choices and canmore easil go systemic.

This is an excellent review on CoV fusion – deals with all the complexities:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3397359/

Bottom line – I think that if you put selection pressure on a Cov without a furin cleavage site in cell culture you could well generate a furin cleavage site after a number of passages (but let's see the data Ron!). It will infect a lot better if it can effectively fuse at the cell surface and doesn't have to rely on endosomal cleavage and receptor mediated endocytosis..

Via Slack, Dr. Garry stated, "you can synthesize bits of genes de novo with perfect precision then add them back in without a trace."[165] This idea was reiterated by Dr. Fouchier, who stated, "[M]olecular biologists like myself can generate perfect copies of viruses without leaving a trace, eg the BAM HI site."[166]

Message

From: R.A.M. Fouchier [redacted]
Sent: 2/8/2020 2:50:00 PM
To: Andrew Rambaut [redacted]; Jeremy Farrar [redacted]
CC: Eddie Holmes [redacted]; Christian Drosten [redacted]
kga1978 [redacted]; rfgarry [redacted]; p.vallance1 [redacted]; collinsf [redacted]
afauci [redacted]; Josie Golding [redacted]; M.P.G. Koopmans [redacted]
Mike Ferguson [redacted]
Subject: Re: [ext] 2019 N-CoV

I do not understand Andrews argument " The sequence data clearly and unambiguously rules out any form of lab construct or engineering of the virus. ". Molecular biologists like myself can generate perfect copies of viruses without leaving a trace, eg the BamHI site. The arguments for and against passaging and engineering are the same if you ask me.
Ron

[165] Message from Robert Garry, Ph.D., Slack (Feb. 6, 2020, 7:09 PM).
[166] E-Mail from Ron Fouchier, Ph.D., Deputy Head of the Erasmus MC Department of Viroscience, Erasmus MC, to Andrew Rambaut, Ph.D., Professor, University of Edinburgh (Feb. 8, 2020, 2:50 PM).

Further, Dr. Garry testified that it would be possible to generate a furin cleavage site in a lab.

Dr. Robert Garry (June 9, 2023)

Q. But a novel coronavirus, if I just bring in a novel coronavirus, its still possible that I could create a furin cleavage site?

A. I mean, its possible. I - - you know, its possible.[167]

Additionally, Dr. Garry testified that a scientist could conduct serial passaging of a virus in animals to generate a furin cleavage site and that this virus would be indistinguishable from a natural one.

Dr. Robert Garry (June 9, 2023)

Q. Would past evolutionary passage in an animal in a laboratory look the same as evolutionary passage in an animal in the wild?

A. In principle, yes. It's a very difficult experiment you are describing though.

Q. Are people capable of conducting that experiment?

A. They're capable of doing it. There would have to be a reason why they would want to do that. And just doing it on some random bat viruses is probably not something that most scientists would consider.

Q. Could you put enough laboratory selection pressure on a novel coronavirus to generate a furin cleavage site?

A. I mean, is it possible? It's in the realm of -- it's something -- I mean most everything is possible, right? Is it probable? Probably not, I would have to say. I mean, in principle, you know, lots of things can happen; you know, unexpected things can happen. But designing an experiment to actually make that happen, I'm not sure that there's any scientist that's really capable of doing that.[168]

Dr. Andersen agreed when asked, "you could put enough pressure on a coronavirus to generate a furin cleavage site?" He responded, "I think as a hypothesis, I think it's a good hypothesis."[169]

[167] Garry TI, *supra* note 77, at 34.
[168] Garry TI, *supra* note 77, at 32-33.
[169] Andersen TI, *supra* note 55, at 159.

No known SARS-related coronavirus or sarbecovirus—the subgenus that COVID-19 belongs to—has a furin cleavage site and none have been found since the beginning of the pandemic. Further, those involved with Proximal Origin believed it is possible to artificially create a furin cleavage site in the lab. When asked if the arguments regarding the furin cleavage site put forth in Proximal Origin ruled out a lab origin, CDR Chretien testified, "no, not in my mind."[170]

3. The Novel Backbone

"Furthermore, if genetic manipulation had been performed, one of the several reverse-genetic systems available for betacoronaviruses would probably have been used. However, the genetic data irrefutably show that SARS-CoV-2 is not derived from any previously used virus backbone."

The Proximal Origin authors are correct that COVID-19 does not derive from any published backbone, but they once again assume that all data has been previously published, a faulty assumption. As noted in the Working Paper, "[r]ecent technological innovations make it easier than ever for scientists to develop new reverse genetics systems."[171] When asked for more detail, CDR Chretien testified:

CDR Jean-Paul Chretien (June 29, 2023)

Q. So, it would be possible that there are novel backbones or novel reverse genetics systems that are out there but not published?

A. Yes.

Q. And even simpler than that, not necessarily a novel backbone, but is it possible that researchers just used an unsequenced or unpublished coronavirus as the backbone?

A. Yes.[172]

Via Slack, the Proximal Origin authors rebuted their own argument. Dr. Andersen wrote, "[j]ust in case people think it is difficult to make a CoV reverse genetics clone from scratch – these guys did it in a week…"[173]

Further, Dr. Andersen wrote, "[o]ne important thing I came across though – for the SARS GoF studies they created a reverse genetics system for their bat virus on a whim. So, Ron's and Christian's argument (which I found to be the strongest) about that not being feasible is not true – they were already creating those."[174]

[170] Chretien TI, *supra* note 146, at 39.
[171] Chretien & Cutlip Working Paper, *supra* note 142.
[172] Chretien TI, *supra* note 146, at 39.
[173] Message from Kristian Andersen, Ph.D., Slack (Feb. 21, 2020 9:05 PM).
[174] Message from Kristian Andersen, Ph.D., Slack (Feb. 2, 2020 6:48 PM).

The Proximal Origin authors did not believe their own arguments against a lab leak as written in Proximal Origin. This is exemplified by comparing the authors' contemporaneous Slack messages and e-mails, media reports, and interview transcripts with the two primary conclusions of Proximal Origin—"we do not believe that any type of laboratory-based scenario is plausible" and "[o]ur analysis clearly show that SARS-CoV-2 is not a laboratory construct or a purposefully manipulated virus."[175]

The Publication of Proximal Origin

On February 6, 2020, Dr. Farrar first suggested publishing Proximal Origin.[176]

Message

From: Edward Holmes [redacted]
Sent: 2/6/2020 2:36:30 AM
To: Kristian G. Andersen [redacted]
CC: Garry, Robert F [redacted]; Andrew Rambaut [redacted]
Subject: Re: Summary - Invitation to edit

From Jeremy.

"Do you think in the report....possible to dampen down further the 'conspiracy' idea and make totally neutral?

Talking with Marion last night and with the WHO meeting next week....both wondering whether actually publishing this sooner, but ruthlessly on the science....is worthwhile to put that flag down..."

Thoughts?

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T
E [redacted]

On February 7, 2020, Dr. Farrar suggested possible journals for publication of Proximal Origin.[177]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[175] Proximal Origin, *supra* note 42.
[176] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Kristian Andersen, Ph.D., Professor, Scripps Research, *et. al.* (Feb. 6, 2020, 2:36 AM)
[177] E-Mail from Jeremy Farrar, Ph.D., Dir. Wellcome Trust, to Edward Holmes, Ph.D., Professor, University of Sydney, *et. al.* (Feb. 7, 2020).

On 7 Feb 2020, at 5:26 pm, Jeremy Farrar [redacted] wrote:

When can you update?

Lancet
Nature
NEJM

Will all review immediately, after quick QC, will share with WHO.

Can I help with any of the editors?

Who will be authors from your side?

Then, right before Proximal Origin was publicly released, it received the final publication push and approval from Dr. Collins. In an email from Dr. Holmes, he recounted Dr. Collins writing, "[t]his is really well done, and I would argue ought to be made public ASAP (Jeremy sent it this morning)."[178]

Message

From: Edward Holmes [redacted]
Sent: 2/16/2020 3:06:49 PM
To: Garry, Robert F [redacted]
CC: Ian Lipkin [redacted]; Kristian G. Andersen [redacted]; Andrew Rambaut [redacted]
Subject: Re: Paper

Just got this from Francis Collins.

"This is really well done, and I would argue ought to be made public ASAP (Jeremy sent it this morning).

Francis"

I'll submit and send to Magda/Clare this morning. If they ok we can then put on bioRxiv and perhaps Virological.org as well?

Cheers,

Eddie

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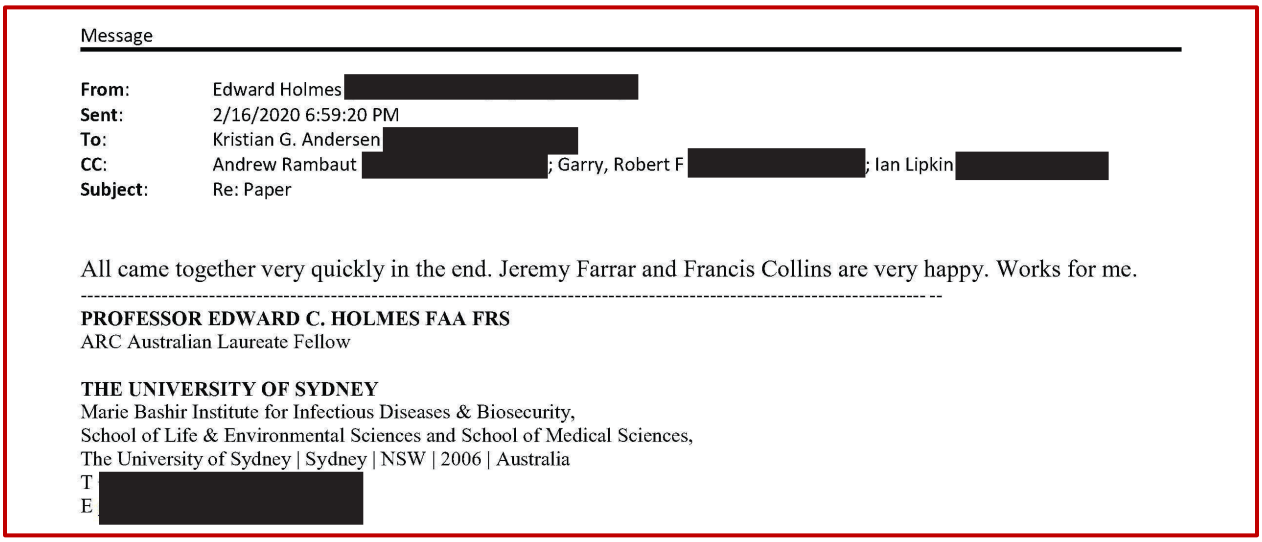
T [redacted]
E

[178] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Robert Garry, Ph.D., Professor, Tulane College of Medicine, *et. al.* (Feb. 16, 2020, 3:06 PM).

Four hours later, according to Dr. Holmes, "[a]ll came together very quickly in the end. Jeremy Farrar and Francis Collins are very happy. Works for me."[179]



Message

From: Edward Holmes [redacted]
Sent: 2/16/2020 6:59:20 PM
To: Kristian G. Andersen [redacted]
CC: Andrew Rambaut [redacted]; Garry, Robert F [redacted]; Ian Lipkin [redacted]
Subject: Re: Paper

All came together very quickly in the end. Jeremy Farrar and Francis Collins are very happy. Works for me.

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T [redacted]
E [redacted]

Proximal Origin Gets Rejected from *Nature*

On February 12, 2020, Dr. Andersen pitched Proximal Origin to *Nature*.[180] In his first pitch, as described above, he wrote, "[p]rompted by Jeremy Farrah [sic], Tony Fauci, and Francis Collins, Eddie Holmes, Andrew Rambaut, Bob Garry, Ian Lipkin, and myself have been working through much of the (primarily) genetic data to provide agnostic and scientifically informed hypothesis around the origins of the virus. We are not write finished with the writeup and we still have some loose ends, but I wanted to reach out to you to see if this might be potentially of interest? We see this more as a commentary/hypothesis, as opposed to a more long-form Letter or Article."[181]

Senior Editor at *Nature* Clare Thomas responded, "Yes please!"[182]

On February 17, 2020, Dr. Holmes, on behalf of Dr. Andersen, submitted a manuscript titled, "The Proximal Origin of SARS-CoV-2" to *Nature* for review.[183] Later that day, Dr. Andersen followed up writing, "[s]orry for contracting you again. The manuscript was put on Virological this morning, which has created some urgency from Wellcome, WHO, and

[179] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Kristian Andersen, Ph.D., Professor, Scripps Research, *et. al.*(Feb. 16, 2020, 6:59 PM).
[180] E-Mail from Kristian Andersen, Ph.D., Professor, Scripps Research, to Clare Thomas, Editor, Nature (Feb. 12, 2020).
[181] *Id.*
[182] E-Mail from Clare Thomas, Editor, Nature, to Kristian Andersen, Ph.D., Professor, Scripps Research (Feb. 13, 2020).
[183] E-Mail from Clare Thomas, Editor, Nature, to Kristian Andersen, Ph.D., Professor, Scripps Research (Feb. 17, 2020).

others…this is an extremely rapidly evolving situation – which has unfortunately been amplified due to some recent "speculations" from parts of the US media."[184]

Ms. Thomas responded, "I have two reviewers looking at it already…"[185]

The Proximal Origin authors, themselves, recommended reviewers. According to Dr. Garry, "[s]o as you know when you submit, you'll need to suggest reviewers to include and exclude. Seems easy – there are some natural choices for both lists."[186] Dr. Holmes responded, "[o]h, yes the reviewers are easy…I think this is a slam dunk."[187] These comments raise serious bias concerns with both the review of Proximal Origin and the scientific peer review process generally. Neither Dr. Andersen nor Dr. Garry knew which suggested reviewers were included or excluded.

On 16 Feb 2020, at 7:36 pm, Garry, Robert F [redacted] wrote:

Yeah I know and that's a good choice for him.

So, as you know when you submit you'll need to suggest reviewers to include and exclude. Seems easy - there are some natural choices for both lists. Nature commentaries are peer reviewed iirc but I'm guessing they'll push this as fast as possible.

Sent from my iPhone

Message

From: Edward Holmes [redacted]
Sent: 2/16/2020 2:38:46 AM
To: Garry, Robert F [redacted]
CC: Ian Lipkin [redacted] Andrew Rambaut [redacted]; Kristian G. Andersen [redacted]
Subject: Re: Paper

External Sender. Be aware of links, attachments and requests.

Oh yes, the reviewers are easy…I think this is a slam dunk.

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The University of Sydney | Sydney | NSW | 2006 | Australia
T [redacted]
E [redacted]

[184] E-Mail from Kristian Andersen, Ph.D., Professor, Scripps Research, to Clare Thomas, Editor, Nature (Feb. 17, 2020).
[185] E-Mail from Clare Thomas, Editor, Nature, to Kristian Andersen, Ph.D., Professor, Scripps Research (Feb. 18, 2020).
[186] E-Mail from Robert Garry, Ph.D., Professor, Tulane College of Medicine, to Edward Holmes, Ph.D., Professor, University of Sydney, *et. al.* (Feb. 16, 2020, 7:36 PM).
[187] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Robert Garry, Ph.D., Professor, Tulane College of Medicine, *et. al.* (Feb. 16, 2020, 2:38 AM).

On February 20, 2020, *Nature* officially rejected Proximal Origin for publication. Ms. Thomas stated, "[w]e've now obtained two ref reports on the paper (appended below), and I've had the opportunity to discuss them with our chief editor Magdalena Skipper. In the light of the advice received I am afraid we have decided that we cannot offer to publish in Nature."[188] The primary reason for denial, as stated by Ms. Thomas, was, "…one of our referees raised concerns (also emphasized to the editors) about whether such a piece would feed or quash the conspiracy theories."[189]

Regarding the denial, Dr. Andersen testified:

Dr. Kristian Andersen (June 16, 2023)

Q. Did you ever get told why *Nature* originally rejected Proximal Origin?

A. They -- I think they rejected the paper because I think the reviewers felt that probably -- I mean, reviewer two was pretty critical about our conclusions of the paper and felt that they should have been stronger, and I think he had relayed those concerns to the editor, and I think that that would have been the reason.

Q. The conclusions that -- what do you mean?

A. Basically, that we -- because, again, we kept the possibilities of -- remember the submitted version to that was open-ended, agnostic as to whether it could have been a lab passage of the two versions of the natural origin that we discuss. And I think the editor probably felt that that was too open-ended. That was clearly what -- especially reviewer two pointed that out in their review, which we disagreed with.[190]

Dr. Garry testified:

Dr. Robert Garry (June 9, 2023)

Q. What were the reasons for the rejection?

A. They -- well, I mean, you can read all the reviews of the paper. They thought that we came down too strongly on the side that the virus had been of possible lab origin. And some of the reviewers wanted us to take that out, and we didn't think that was appropriate.[191]

[188] E-Mail from Clare Thomas, Editor, Nature, to Kristian Andersen, Ph.D., Professor, Scripps Research (Feb. 20, 2020).
[189] *Id.*
[190] Andersen TI, *supra* note 55, at 186.
[191] Garry TI, *supra* note 77, at 176,

After the denial, Ms. Thomas suggested submitting Proximal Origin to *Nature Medicine*.[192]

Proximal Origin Gets Accepted at *Nature Medicine*

On February 27, 2020, Dr. Andersen submitted Proximal Origin to *Nature Medicine*.[193] In his submission, Dr. Andersen wrote:

> I believe Clare over at Nature might have mentioned our commentary on the proximal origins of the hCoV-19 virus last week. We have been incorporating some critical changes to the reviewer's comments, so I just wanted to reach out to you to see if you're still interested in having a look at this manuscript? We're still incorporating a few changes but will have all of this wrapped up shortly as we're on a tight deadline - the media interest in this has been enormous and hasn't slowed down (we have refrained from commenting until formal publication). The public interest has also been very high, with more than 65,000 reads of the blog post version over the last week.[194]

After having been denied by *Nature* for not downplaying the possibility of a lab leak strongly enough, the authors decided to make this submission stronger.

> **Dr. Kristian Andersen (June 16, 2023)**
>
> Q. You, and correct me if I'm wrong, said something along the lines earlier that the line: We do not believe that any type of laboratory-based scenario is plausible was added at some point?
>
> A. Correct. That was added to the final version of -- this was added after it went over to Nature Medicine, yes.
>
> Q. Did Nature Medicine add the line?
>
> A. No.
>
> Q. How did that process play out? How did that line get added?
>
> A. That's based on our edits to the paper. Again, as the editor at Nature Medicine states, is that he thought that the paper had grown significantly since the one he had seen from Nature. We had to shorten it. You need to trim this back down, more or less, to the size

[192] E-Mail from Clare Thomas, Editor, Nature, to Kristian Andersen, Ph.D., Professor, Scripps Research (Feb. 20, 2020).
[193] E-Mail from Kristian Andersen, Ph.D., Professor Scripps Research, to Joao Monterio, Editor, Nature Medicine (Feb. 27, 2020).
[194] *Id.*

> of the Nature version while retaining the major changes in response to the reviewers. And some of the responses to the reviewers was that the reviewer felt that we could be more specific on, for example, that lab origins were less likely than we initially entertained, and I agreed with that. I think we all agree with that, and those were changes that we incorporated. So that includes that we don't believe that any type of lab origin is plausible. It's something that was added in response to the reviewers, our own thinking of the topic, and then getting it published in Nature Medicine, as opposed to Nature.[195]

On March 5, 2020, *Nature Medicine* accepted Proximal Origin for publication.[196]

The Anonymous Whistleblower to Jon Cohen

On July 25, 2020, an anonymous whistleblower emailed Mr. Jon Cohen, a reporter for *Science* magazine, and alleged that Proximal Origin plagiarized the arguments of others from the February 1 conference call.[197] The whistleblower also alleged that this was one of the reasons that *Nature* rejected the paper.[198] Mr. Cohen forwarded these claims to Dr. Andersen and Dr. Holmes and said, "[h]ere's what one person who claims to have inside knowledge is saying behind your backs…"[199]

Dr. Andersen and Dr. Holmes then drafted a response to Mr. Cohen and forwarded their draft to Dr. Fauci and Dr. Farrar for approval.[200] In this email, Dr. Andersen expressed concerns about confirming that the February 1 Conference Call took place, stating, "[w]e need to reply back to Jon, which would include confirming that this meeting took did indeed take place with you and Jeremy present. Please let me know if you have any comments or concerns in this regard."[201]

In response to Dr. Andersen, Dr. Farrar replied, "[c]an we get the sequence of events right and agreed before a substantive reply goes back to Jon?"[202] Dr. Holmes, responded with a revised draft and wrote, "[f]or Tony's benefit a revised draft of the email to Jon is pasted below."[203]

While the identity of the anonymous whistleblower is still unknown, the Proximal Origin authors had their own suspicions. Dr. Holmes opined, "…I'm 100% sure it was Ron who leaked

[195] Andersen TI, *supra* note 55, at 186-187.
[196] E-Mail from Nature Medicine, to Kristian Andersen, Ph.D., Professor, Scripps Research (Mar. 5, 2020).
[197] E-Mail from Jon Cohen, Reporter, Science, to Kristian Andersen, Ph.D., Professor, Scripps Research, & Edward Holmes, Ph.D., Professor University of Sydney (July 25, 2020).
[198] *Id.*
[199] *Id*.
[200] E-Mail from Kristian Andersen, Ph.D., Professor, Scripps Research, to Anthony Fauci, M.D., Dir., Nat'l Inst. Of Allergy & Infectious Diseases, *et. al.,* (July 28, 2020).
[201] *Id.*
[202] E-Mail from Jeremy Farrar, Ph.D., Dir., Wellcome Trust, to Kristian Andersen, Ph.D., Professor Scripps Research, *et. al.* (July 28, 2020).
[203] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Jeremy Farrar, Ph.D., Dir. Wellcome Trust, *et. al.* (July 28, 2020).

it – he was the most angry – and I still think it was like Baric who emailed Jon Cohen."[204] Dr. Rambaut responded, "I agree – most likely Ron doing the leaking."[205]

On 28 Jul 2020, at 6:21 pm, Andrew Rambaut [redacted] wrote:

I agree - most likely Ron doing the leaking. Whoever it was that talked to the emailer was indignant that 'non-coronavirus-experts' were involved. I can't see any of the others having this sort of pompous, arrogant view of the world. Marion approached me well after this to help analyse the Dutch data. Christian I have worked with before on MERS. I doubt even that Ron was that bothered - probably just told the story to whoever it was and misremembered or 'enhanced' it for effect.

A

On 28 Jul 2020, at 03:58, Edward Holmes [redacted] wrote:

Pohlmann as on it and very good. Christian was also v. interested in the furin cleavage site (I've other emails).

Despite this, I'm 100% sure it is Ron who leaked it - he was the most angry - and I still think it was like Baric who emailed Jon Cohen.

I just thought "I would conclude that a follow-up discussion on the possible origin of 2019-nCoV would be of much interest" was very interesting.

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The University of Sydney | Sydney | NSW | 2006 | Australia

Dr. Baric denied being the anonymous individual that e-mailed Mr. Cohen.

Dr. Ralph Baric (January 22, 2024)

Q. After the fact -- and then there's a reporter at Science Magazine named John Cohen.

A. I know him.

Q. He put out some emails after the fact of an anonymous person that claimed that the "proximal origin" authors plagiarized some ideas and went a little bit too far. Are you aware of those emails?

A. John contacted me.

[204] E-Mail from Edward Holmes, Ph.D., Professor, University of Sydney, to Kristian Andersen, Ph.D., Professor, Scripps Research, *et. al.* (July 28, 2020, 3:58 PM).
[205] E-Mail from Andrew Rambaut, Ph.D., Professor, University of Edinburgh, to Edward Holmes, Ph.D., Professor, University of Sydney, *et. al.* (July 28, 2020, 6:21 PM).

Q. Were you the –

A. No, I was not. I was not. I was building suspense.

Q. So Dr. –

A. And it worked.

Q. It did. Part of it is because Dr. Holmes thinks you were the one that contacted John Cohen.

A. Well, that's why he may say it. He and -- I'm forgetting his name, sorry -- Andersen. If that's what they thought, he may have been really irritated with me if he felt that it was me, but it was not.

Q. What did Mr. Cohen contact you about?

A. He was asking me the same question you asked me, was I the author of that statement? And I said, no, I was not.

Q. Do you know who is?

A. No, I don't.[206]

The Critical Reception of Proximal Origin

On February 19, 2020, Proximal Origin was cited in the letter in *The Lancet* titled, "Statement in support of the scientists, public health professionals, and medical professionals of China combatting COVID-19."[207] Proximal Origin was cited as proof "this coronavirus originated in wildlife."[208]

On March 17, 2020, Dr. Andersen's employer, Scripps Research, put out a press release regarding Proximal Origin entitled, "The COVID-19 coronavirus pandemic has a natural origin, scientists say."[209] Dr. Andersen is quoted in this release saying, "…we can firmly determine that SARS-COV-2 originated through natural process."[210] Dr. Farrar's organization, The Wellcome Trust, is also quoted in the release, stating, "they conclude that the virus is the product of natural evolution."[211]

NIH and NIAID were keenly anticipating the release of Proximal Origin. On February 19, 2020, the NIAID Office of Communications spoke internally regarding the paper and stated,

[206] Baric TI, *supra* note 39, at 124-125.
[207] Charles Calisher, Ph.D., *et. al., Statement in support of the scientists, public health professionals, and medical professionals of China combatting COVID-19,* THE LANCET (Feb. 19, 2020).
[208] *Id.*
[209] *The COVID-19 coronavirus epidemic has a natural origin, scientists say*, SCRIPPS RESEARCH (Mar. 17, 2020).
[210] *Id.*
[211] *Id.*

"[t]he Office of Communications asked if we could alert them if this paper is accepted in a peer review journal. Do you know if the authors have submitted it to a journal?"[212]

From: Coleman, Amanda (NIH/NIAID) [C] [redacted]
Sent: Wednesday, February 19, 2020 1:21 PM
To: Shabman, Reed (NIH/NIAID) [E] [redacted]
Cc: Brown, Liliana (NIH/NIAID) [E] [redacted]
Subject: RE: COVID-19 preprint of interest

Hi Reed – The Office of Communications asked if we could alert them if this paper is accepted in a peer reviewed journal. Do you know if the authors have submitted it to a journal?

Thank you,

Amanda Coleman [C]
[redacted]

An NIH employee responded, "I reached out to Kristian and team…the text is submitted to Nature. Kristian suggests that the office of Communication can communicate directly with Chris Emery [Scripps Research]."[213]

From: Shabman, Reed (NIH/NIAID) [E]
Sent: Wednesday, February 19, 2020 3:30 PM
To: Coleman, Amanda (NIH/NIAID) [C] [redacted]
Cc: Brown, Liliana (NIH/NIAID) [E] [redacted] Chris Emery [redacted]
Subject: RE: COVID-19 preprint of interest

Hi Amanda,

I reached out to Kristian and team and copied his response below in italics. As you can see from his note, the text is submitted to Nature. Kristian suggests that the Office of Communications can communicate directly with Chris Emery (copied here).

REV0002496

Thanks,

Reed

Yes, it's been submitted for peer review (in Nature) and we are holding off on giving further comments to the media until it's been through that and published. Chris Emery from our communications department (cc'd here) is taking the lead on creating a press release / summary in lay language, as well as a Q&A with questions the public and policy makers might have - Wellcome is involved as well to help out. If there's interest on NIAID's side, I'm sure Chris and the team would welcome coordination/collaboration, so if you can please reach out to him directly.

Best,
Kristian

[212] E-Mail from Amanda Coleman, Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. Of Health, to Reed Shabman, Program Office, Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. Of Health (Feb. 19, 2020, 1:21 PM).
[213] E-Mail from Reed Shabman, Program Office, Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. Of Health, to Amanda Coleman, Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. Of Health (Feb. 19, 2020, 3:30 PM).

On March 26, 2020, Dr. Collins wrote a blog post for the NIH regarding Proximal Origin.[214] Dr. Collins wrote, "[a] new study debunks such claims by providing scientific evidence that this novel coronavirus arose naturally."[215] Dr. Collins concluded, "[e]ither way, this study leaves little room to refute a natural origin for COVID-19."[216]

On April 16, 2020, more than two months after the original February 1 Conference Call and a month after Proximal Origin was published, Dr. Collins emailed Dr. Fauci and expressed dismay that Proximal Origin did not successfully squash the lab leak theory. He stated, "I hoped the Nature Medicine article on the genomic sequence of SARS-CoV-2 would settle this…"[217] Then Dr. Collins asked Dr. Fauci, "[w]ondering if there is something NIH can do to help put down this very destructive conspiracy…Anything more we can do?"[218]

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[214] Francis Collins, *Genomic Study Points to Natural Origin of COVID-19*, NAT'L INSTS. OF HEALTH (Mar. 26, 2020).
[215] *Id.*
[216] *Id.*
[217] E-Mail from Francis Collins, Dir., Nat'l Insts. Of Health, to Anthony Fauci M.D., Dir. Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. Of Health (Apr. 16, 2020, 10:45 PM).
[218] *Id.*

From: Fauci, Anthony (NIH/NIAID) [E]
To: Collins, Francis (NIH/OD) [E]
Subject: RE: conspiracy gains momentum
Date: Thursday, April 16, 2020 10:45:00 PM

Francis:

I would not do anything about this right now. It is a shiny object that will go away in time.

Best,

Tony

From: Collins, Francis (NIH/OD) [E] [redacted]
Sent: Thursday, April 16, 2020 5:02 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]; Lane, Cliff (NIH/NIAID) [E] [redacted] Burklow, John (NIH/OD) [E] [redacted]
Subject: conspiracy gains momentum

Wondering if there is something NIH can do to help put down this very destructive conspiracy, with what seems to be growing momentum:

https://www.mediaite.com/tv/foxs-bret-baier-sources-increasingly-confident-coronavirus-outbreak-started-in-wuhan-lab/

I hoped the Nature Medicine article on the genomic sequence of SARS-CoV-2 would settle this. But probably that didn't get much visibility.

Anything more we can do? Ask the National Academy to weigh in?

Francis

mittee on the Coronavirus Pandemic Pursuant to Oversight Reques
Permission from Department of Health and Human Services

Dr. Collins testified that "Nature Medicine article" was in reference to Proximal Origin.[219] The next day, on April 17, 2020, Dr. Fauci cited Proximal Origin from the White House podium.

White House Press Conference (April 17, 2023)

Q. Mr. President, I wanted to ask Dr. Fauci: Could you address these suggestions or concerns that this virus was somehow manmade, possibly came out of a laboratory in China?

Dr. Fauci. There was a study recently that we can make available to you, where a group of highly qualified evolutionary

[219] Transcribed Interview of Francis Collins, M.D., Ph.D., former Dir., Nat'l Insts. of Health (Jan. 12, 2024) [hereinafter "Collins TI"].

> virologists looked at the sequences there and the sequences in bats as they evolve. And the mutations that it took to get to the point where it is now is totally consistent with a jump of a species from an animal to a human. So, I mean, the paper will be available — I don't have the authors right now, but we can make that available to you.[220]

After the briefing, a reporter directly asked which paper Dr. Fauci cited and was then sent Proximal Origin. The reporter wrote, "Dr. Fauci on Friday said he would share a scientific paper with the press on the origin of the coronavirus. Can you please help me get a copy of that paper?"[221]

On Apr 19, 2020, at 2:21 PM, Bill Gertz Redacted wrote:

Katie,

Dr. Fauci on Friday said he would share a scientific paper with the press on the origin of the coronavirus. Can you please help me get a copy of that paper? Thanks in advance.

Bill Gertz

National Security Correspondent
@BillGertz | direct Redacted
TheGertzFile.com

<twtlogo.jpg>

3600 New York Ave NE | Washington DC, 20002

the Coronavirus Pandemic Pursuant
n from Department of Health and

Dr. Fauci responded, "[h]ere are the links to the scientific papers and a commentary about the scientific basis of the origins of SARS-Cov-2" and lists Proximal Origin.[222]

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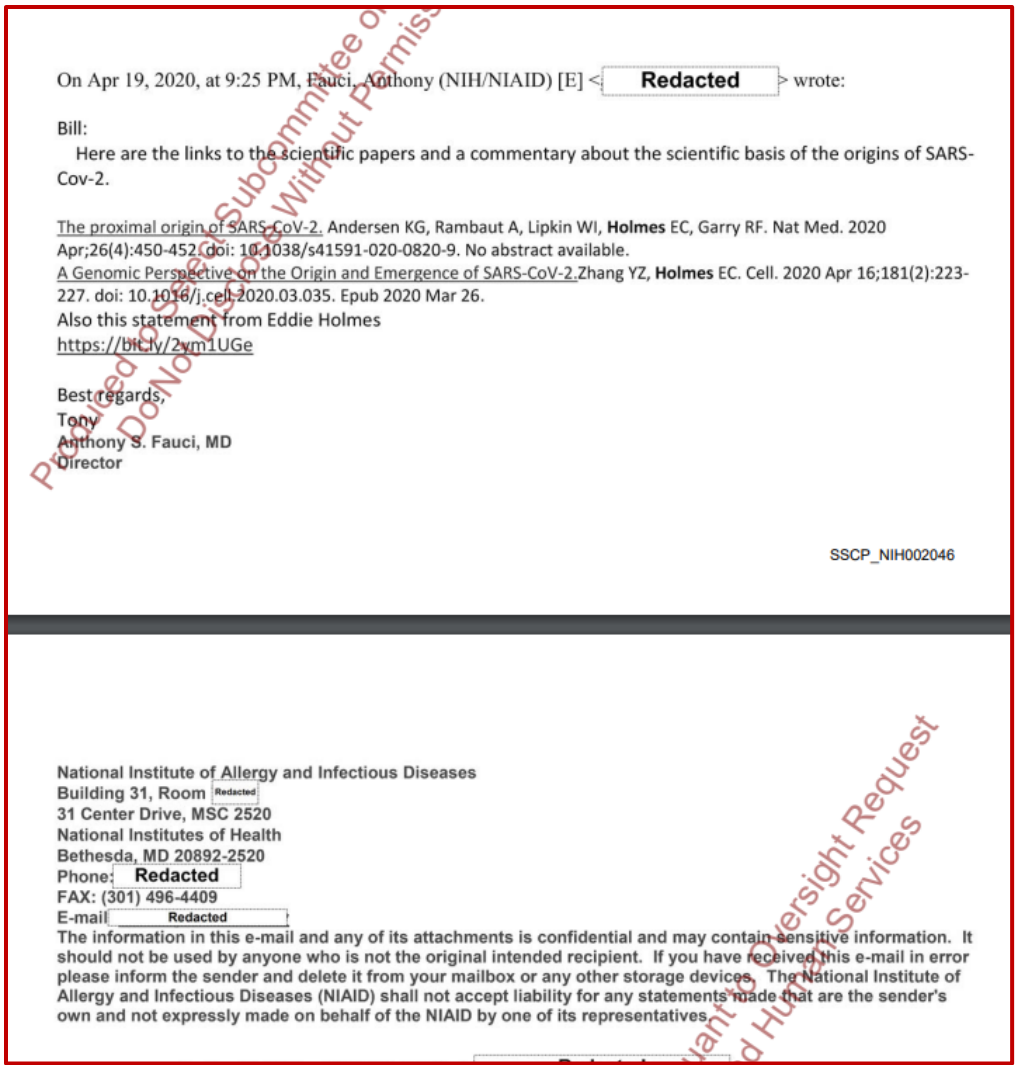
[220] Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing, The White House (Apr. 17, 2020) [hereinafter "Remarks by President Trump April 17, 2020"].
[221] E-Mail from Bill Gertz, Correspondent, The Wash. Times, to Anthony Fauci, M.D., Dir. Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. Of Health (Apr. 19, 2020, 2:21 PM).
[222] E-Mail from Anthony Fauci, M.D., Dir. Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. Of Health, to Bill Gertz, Correspondent, The Wash. Times (Apr. 19, 2020, 9:25 PM).



On Apr 19, 2020, at 9:25 PM, Fauci, Anthony (NIH/NIAID) [E] <Redacted> wrote:

Bill:
Here are the links to the scientific papers and a commentary about the scientific basis of the origins of SARS-Cov-2.

The proximal origin of SARS-CoV-2. Andersen KG, Rambaut A, Lipkin WI, **Holmes** EC, Garry RF. Nat Med. 2020 Apr;26(4):450-452. doi: 10.1038/s41591-020-0820-9. No abstract available.
A Genomic Perspective on the Origin and Emergence of SARS-CoV-2.Zhang YZ, **Holmes** EC. Cell. 2020 Apr 16;181(2):223-227. doi: 10.1016/j.cell.2020.03.035. Epub 2020 Mar 26.
Also this statement from Eddie Holmes
https://bit.ly/2ym1UGe

Best regards,
Tony
Anthony S. Fauci, MD
Director

SSCP_NIH002046

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Produced to Select Subcommittee on Weaponization of the Federal Government
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Pursuant to Congressional Oversight Request
House Committee on Health and Human Services

Dr. Fauci later stated he may not have ever actually read Proximal Origin.[223] This raises questions of why he would cite a paper, he did not even read, from the White House podium as proof COVID-19 was not the result of a lab leak.

Dr. Collins testified that despite his e-mail suggesting he desired more action to "put down" the lab leak hypothesis, he did not instruct Dr. Fauci to cite Proximal Origin from the White House.[224] Dr. Fauci also testified that his statement at the White House was not in response to Dr. Collins' e-mail.[225]

On January 9, 2024, Mr. Don McNeil, former science and health reporter for the *New York Times*, published "The Wisdom of Plagues: Lessons from 25 Years of Covering Pandemics." In Wisdom of Plagues, Mr. McNeil recounted:

[223] Megan Stack, *Dr. Fauci Could Have Said a Lot More*, THE N.Y. TIMES (Mar. 28, 2020).
[224] *See* Collins TI, *supra* note 219.
[225] *See*, Transcribed Interview of Anthony Fauci, M.D., former Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Jan. 8, 2024) [hereinafter "Fauci TI 1"].

> Far more serious errors occur when sources deliberately deceive reporters. In late July 2023, this book was almost in print when I learned, from emails and Slack chats [released] by the Congressional Subcommittee on the Coronavirus Pandemic and posted on *Public*, a Substack magazine, that I was the victim of deception in the pandemic's earliest days. In February 2020, four eminent scientists whom I respected had discussed with each other various ways to throw me off track when I asked whether it was possible that the virus had been manipulated in a lab or might have leaked from one. Their efforts affected how I viewed the controversy over Covid's origins and how the *Times* covered it. My publisher allowed me to quickly rewrite this chapter.[226]

Mr. McNeil also confirmed that the Proximal Origin authors' deception altered how the New York Times reported on COVID-19 origins.

[226] Donald G. McNeil, Jr., The Wisdom of Plagues: Lessons from 25 Years of Covering Pandemics (Simon & Schuster, 2024).

II. The Failures of EcoHealth Alliance, Inc.

EcoHealth is a non-profit scientific research organization that is primarily funded by U.S. taxpayer dollars. Its President is Dr. Daszak, and both EcoHealth and Dr. Daszak are long time collaborators with the WIV and Dr. Shi. Beginning in April 2020, NIH investigated both EcoHealth and Dr. Daszak for numerous grant policy violations and accusations of facilitating dangerous research at the WIV.

Starting in February 2023, the Select Subcommittee began its own investigation into EcoHealth.[227] In July 2023, HHS debarred the WIV for a period of 10 years for non-compliance.[228] Further, in May 2024, as a direct result of the Select Subcommittee's investigation, HHS immediately suspended and proposed for debarment both EcoHealth, as an institution, and Dr. Daszak, as an individual.[229] As of December 4, 2024, neither EcoHealth's nor Dr. Daszak's debarment is finalized. Both NIH and Dr. Fauci support the debarment of EcoHealth.

Dr. Lawrence Tabak (November 14, 2024)

Q. And does NIH still support the debarment of EcoHealth and Dr. Daszak?

A. We do. And we have provided all necessary documents to the Department.[230]

Dr. Anthony Fauci (June 3, 2024)

Q. During previous TIs and hearings, when asked if they supported every one of these actions…, both Dr. Collins and Dr. Tabak said yes. Sitting here today, do you support the suspension and debarment of EcoHealth?

A. Yes.[231]

FINDING: EcoHealth Alliance, Inc. Facilitated Gain-of-Function Research at the Wuhan Institute of Virology.

[227] Letter from Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, to Peter Daszak, Ph.D., Pres., EcoHealth Alliance, Inc. (Feb. 13, 2023).
[228] Letter from Deputy Assistant Sec'y for Acquisitions, Suspension and Debarment Official, to Yanyi Wang, Dir., Wuhan Institute of Virology (July 18, 2023).
[229] Letter from Henrietta Katrina Brisbon, Suspension and Debarment Official and Deputy Assistant Sec'y for Acquisitions, HHS, to Peter Daszak, President, EcoHealth Alliance, Inc. (May 2024).
[230] Preparing for the Next Pandemic: Lessons Learned and the Path Forward: Hearing Before Select Subcomm. on Coronavirus Pandemic, 118th Cong. 2, at 19 (Nov. 14, 2024) (testimony of Dr. Tabak) [hereinafter "Preparing for the Next Pandemic"].
[231] A Hearing with Dr. Anthony Fauci: Hearing Before Select Subcomm. on Coronavirus Pandemic, 118th Cong. 2, at 122 (June 3, 2024) [hereinafter "Fauci Hearing"]. (The actions referenced in this question refer to NIH's enforcement and oversight actions preceding the 2024 suspension and debarment.)

What Is Gain-Of-Function Research?

The term gain-of-function research encompasses a wide swath of life sciences research, a subset of which involves creating potential pandemic pathogens. The meaning to the public versus the scientific community is different and ever shifting, especially as federal government oversight policies and procedures have shifted. However, the term gain-of-function is not tied to any specific policy or oversight framework and, instead, has a long-established lay definition.

Throughout this investigation, the Select Subcommittee found the term "gain-of-function" could mean something completely different to one person in the field than to another person simply using the term. In fact, different experts also have different understandings of the term. Consequently, a nuanced understanding of the term is essential to facilitate effective oversight and understanding of this type of research.

As of October 19, 2020, according to the NIH website, gain-of-function meant "a type of research that modifies a biological agent so that it confers a new or enhanced activity to that agent."[232]

> Gain-of-Function Research
>
> The term gain-of-function (GOF) research describes a type of research that modifies a biological agent so that it confers new or enhanced activity to that agent. Some scientists use the term broadly to refer to *any* such modification. However, not all research described as GOF entails the same level of risk. For example, research that involves the modification of bacteria to allow production of human insulin, or the altering of the genetic program of immune cells in CAR-T cell therapy to treat cancer generally would be considered low risk. The subset of GOF research that is anticipated to enhance the *transmissibility* and/or *virulence* of potential pandemic pathogens, which are likely to make them more dangerous to humans, has been the subject of substantial scrutiny and deliberation. Such GOF approaches can sometimes be justified in laboratories with appropriate biosafety and biosecurity controls to help us understand the fundamental nature of human-pathogen interactions, assess the pandemic potential of emerging infectious agents, and inform public health and preparedness efforts, including surveillance and the development of vaccines and medical countermeasures. This research poses biosafety and biosecurity risks, and these risks must be carefully managed. When supported with NIH funds, this subset of GOF research may only be conducted in laboratories with stringent oversight and appropriate biosafety and biosecurity controls to help protect researchers from infection and prevent the release of microorganisms into the environment.

This definition was confirmed by multiple witnesses interviewed by the Select Subcommittee.

Dr. Hugh Auchincloss (Dec. 20, 2023)

Q. So, this is the NIH website for gain-of-function research involving potential pandemic pathogens, and this version was last updated July 12, 2021. There has since been a new version, and under the header "Gain-of-Function Research" is that definition that I just read to you. It does have the qualifier, not all research described as gain-of-function entails the same level of risk, and I guess one of the kind of semantics here is that what a layperson thinks of as gain-of-function, I think falls under this definition: Any research that attributes a new attribute to a biological agent, whether it's taking avian influenza virus that can't infect humans or making it able to infect humans or

[232] *Gain-of-Function Research Involving Potential Pandemic Pathogens*, NAT'L INSTS. OF HEALTH (last updated July 12, 2021) (last accessed Oct. 19, 2021) (archived version on file with Select Subcomm. Staff).

taking a bat Coronavirus that can't infect mice and making it infect mice, either of which would qualify as gain-of-function under that definition.

Do you agree?

A. I do, and I think that this is making the same points that I've been making earlier. There's gain-of-function which is common in virology and that's not the same as the gain-of-function research of concern.[233]

Dr. Lawrence Tabak (Jan. 5, 2024)

Q. …My, kind of, understanding is that there's -- it's a complicated definition. There's a lot of different pieces to it. There are pieces that NIH regulates; there's pieces that HHS regulates. There are pieces that have dual-use problems. So, I'm going to run through each definition, and you just tell me if I'm kind of on the right page. The high-level gain-of-function, as was defined by NIH: a type of research that modifies a biological agent so that it confers new or enhanced activity to that agent.

Is that right?

A. It -- as an agent, yes.[234]

In addition to the above definition, the federal government requires that certain types of gain-of-function research receive further oversight and review. In 2014 OSTP determined that a subset of gain-of-function research needed further regulation and paused all new federal funding for that type of research [hereinafter "2014 OSTP Pause"].

New USG funding will not be released for gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.[235]

[233] Transcribed Interview of Hugh Auchincloss, M.D., Dep. Dir., Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. of Health, at 100-101 (Dec. 20, 2023) [hereinafter "Auchincloss TI"].
[234] Tabak TI, *supra* note 83, at 27.
[235] U.S. GOVERNMENT GAIN-OF-FUNCTION DELIBERATIVE PROCESS AND RESEARCH FUNDING PAUSE ON SELECTED GAIN-OF-FUNCTION RESEARCH INVOLVING INFLUENZA, MERS, AND SARS VIRUSES, OFFICE OF SCIENCE AND TECH. POLICY, WHITE HOUSE (Oct. 17, 2014).

This definition is clear—it is not a pause on all gain-of-function research, but on a specific subset. Therefore, it is possible for research to qualify as gain-of-function without qualifying for the 2014 OSTP Pause.

In 2017, as a result of and replacing the 2014 OSTP Pause, HHS released the "Framework for Guiding Funding Decisions About Proposed Research involving Enhanced Potential Pandemic Pathogens (P3CO)" [hereinafter "P3CO Framework"].[236] Similar to the 2014 OSTP Pause, the P3CO Framework did not apply to all gain-of-function research but only a specific subset.

The P3CO Framework applies to "[p]roposed intramural and extramural life sciences research that is being considered for funding and that has been determined by the funding agency as reasonably anticipated to create, transfer, or used enhanced PPPs [potential pandemic pathogens]…"[237] A PPP is defined as a pathogen that:

> (1) "is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations" and
>
> (2) "is likely highly virulent and likely to cause significant morbidity and/or mortality in humans."[238]

An enhanced PPP—the type of pathogen the P3CO Framework is designed to oversee—is defined as a potential pandemic pathogen "resulting from the enhancement of the transmissibility and/or virulence of a pathogen."[239] This applies to only a very narrow subset of research. In fact, out of all the grants issued since the P3CO Framework went into effect, HHS has only reviewed three potential studies that fall under this definition.[240] Again, the P3CO Framework is clear—it only applies to a small subset of gain-of-function research. Therefore, it is possible for research to qualify as gain-of-function without qualifying for the P3CO Framework.

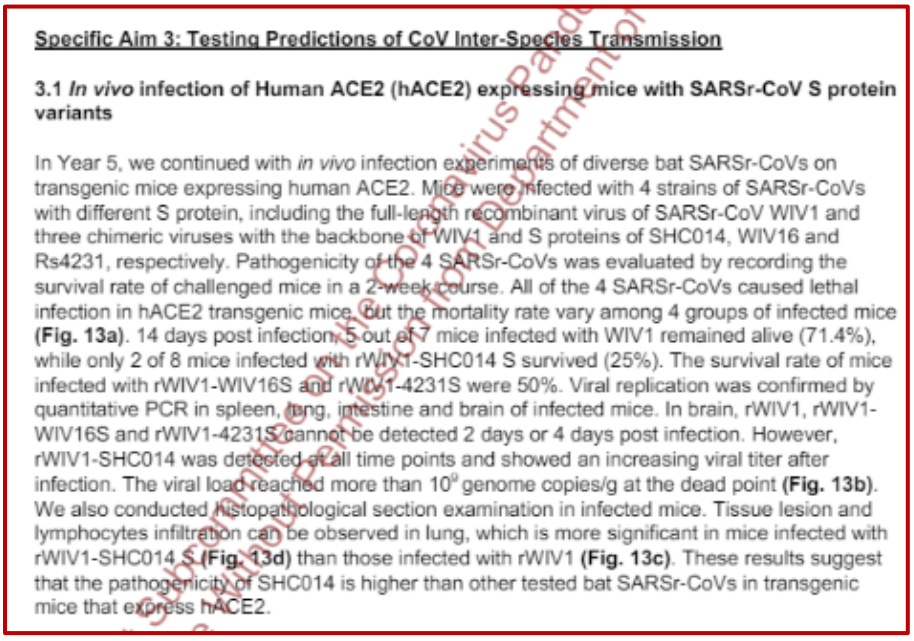
> **Dr. Lawrence Tabak (Jan. 5, 2024)**
>
> Q. Can there be a subset of research that would qualify under that definition of modifying -- of providing a new function to a biological agent --
>
> A. Uh-huh.

[236] FRAMEWORK FOR GUIDING FUNDING DECISIONS ABOUT PROPOSED RESEARCH INVOLVING ENHANCED POTENTIAL PANDEMIC PATHOGENS, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2017).
[237] *Id.*
[238] *Id.*
[239] *Id.*
[240] *Research Involving Enhanced Potential Pandemic Pathogens,* NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS. (last updated June 5, 2023) (last accessed Apr. 23, 2024).

Q.	-- without falling under the categories of being regulated by the P3CO?
A.	Absolutely. [241]

Applying the Definition of Gain-Of-Function to EcoHealth's Reported Experiments.

The Select Subcommittee endeavored to determine if research facilitated by EcoHealth—paid for with U.S. taxpayer dollars—and conducted in Wuhan by the WIV qualified as gain-of-function research. The research in question was published by EcoHealth in its Year 5 Research Performance Progress Reports (RPPR) [hereinafter "Year 5 Report"].[242]



Specific Aim 3: Testing Predictions of CoV Inter-Species Transmission

3.1 *In vivo* infection of Human ACE2 (hACE2) expressing mice with SARSr-CoV S protein variants

In Year 5, we continued with *in vivo* infection experiments of diverse bat SARSr-CoVs on transgenic mice expressing human ACE2. Mice were infected with 4 strains of SARSr-CoVs with different S protein, including the full-length recombinant virus of SARSr-CoV WIV1 and three chimeric viruses with the backbone of WIV1 and S proteins of SHC014, WIV16 and Rs4231, respectively. Pathogenicity of the 4 SARSr-CoVs was evaluated by recording the survival rate of challenged mice in a 2-week course. All of the 4 SARSr-CoVs caused lethal infection in hACE2 transgenic mice, but the mortality rate vary among 4 groups of infected mice **(Fig. 13a)**. 14 days post infection, 5 out of 7 mice infected with WIV1 remained alive (71.4%), while only 2 of 8 mice infected with rWIV1-SHC014 S survived (25%). The survival rate of mice infected with rWIV1-WIV16S and rWIV1-4231S were 50%. Viral replication was confirmed by quantitative PCR in spleen, lung, intestine and brain of infected mice. In brain, rWIV1, rWIV1-WIV16S and rWIV1-4231S cannot be detected 2 days or 4 days post infection. However, rWIV1-SHC014 was detected at all time points and showed an increasing viral titer after infection. The viral load reached more than 10^9 genome copies/g at the dead point **(Fig. 13b)**. We also conducted histopathological section examination in infected mice. Tissue lesion and lymphocytes infiltration can be observed in lung, which is more significant in mice infected with rWIV1-SHC014 S **(Fig. 13d)** than those infected with rWIV1 **(Fig. 13c)**. These results suggest that the pathogenicity of SHC014 is higher than other tested bat SARSr-CoVs in transgenic mice that express hACE2.

The Year 5 Report describes an experiment in which the WIV infected transgenic mice with four different coronaviruses, three of which were chimera or recombinant viruses with different spike proteins. The WIV then measured the pathogenicity of the novel laboratory created viruses as compared to the control, which was a full-length backbone of WIV1. The pathogenicity of the three chimeras was then compared to the control—the full-length backbone of WIV1.

In the experiment, the survival rate of mice infected with WIV1 was 71.4 percent while the survival rate of the mice infected with one of the chimeric viruses (WIV1-SHC014) was just 25 percent. Therefore, the laboratory generated chimera was more pathogenic than the control virus and the mice infected with that chimera became sicker.

[241] Tabak TI, *supra* note 83, at 29.
[242] Interim Research Performance Progress Report, EcoHealth Alliance, Inc., at 15 (Aug. 3, 2021).

In the October 20, 2021 letter to Mr. Comer, Dr. Tabak described this experiment and its result as "unexpected."[243] Regardless of whether the results were expected or not, it appears this experiment would constitute gain-of-function research.

Dr. Lawrence Tabak (Jan. 5, 2024)

Q. NIH has said a lot that the experiment in the EcoHealth grant was not gain-of-function research, that it didn't qualify. Did NIH mean it wasn't ePPP research?

A. It is certainly an example of generic gain-of-function, if that's what you mean.

Q. Yes. So, I'm trying to get at, like, words matter. And using a term that has an established definition, "gain-of-function" -- it's on the NIH's website –

A. Right.

Q. -- has an established definition, that when people say that what EcoHealth did was not gain-of-function research, that's not true. It's not gain-of-function research of concern or that HHS would regulate. Is that fair?

A. That is fair. And I have always, when asked, tried to make that distinction.

Q. All right.

A. Because, as you point out, there's lots of gain-of-function research, and, as is written here, however, not all such research entails the same level of risk.

Q. And I agree with that. I'm just –

A. Yeah.

Q. When there's such a -- like, I don't remember the infection count or the death toll in 2021. And origins has been such a hot-button issue. But, like, when I write things for my bosses that are going to go out and speak or if I was prepping someone for congressional testimony, I'd want to make sure that they're using the right phrases. And whenever we've talked to NIH -- I think I was briefed by you once; it might've been on this letter -- maybe outside of that, we've heard

[243] Letter from Lawrence Tabak, D.D.S., Ph.D., Principal Dep. Dir., Nat'l Insts. of Health to Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform (October 20, 2021).

"NIH did not fund gain-of-function research in Wuhan," period. That's, at best, misleading.

A. I have always tried to make sure that whoever is asking the question is speaking about gain-of-function research of concern. I can only speak for how I'm trying to answer questions of this type. Because you're right, words matter.

Q. And I won't harp too long, but just -- you would agree, what's described in this letter, what's described in the EcoHealth year progress report, would fit the definition -- the broad definition of gain-of-function research?

A. The generic, broad description of what gain-of-function is, yes.[244]

Dr. Ralph Baric (Jan. 22, 2024)

Q. Dr. Baric, you've read the year 5 paragraph now, the in vivo infection where five of the seven mice infected with just the WIV1 backbone survived, but only two of the eight mice infected with the WIV1 SHC014 [survivied].

A. You should be able to do the statistics on that, and it should show that there's a statistical difference, which means there was an increase in virulence and the entire review process would have been triggered.

***

Q. So, my question is, and we've gotten different answers on everything, and it depends on if you're using the P3 definition or whatever definition. This reads like gain-of-function to me.

A. Okay. So what year was this? I just want to make sure I'm in the right gain-of-function regulation.

Q. 2019.

A. So, it's the NSABB regulation…So based on those regulations, yes, this is -- as my interpretation, is that, yes, these would be exempt. But is it a gain-of-function phenotype? Absolutely. You can't argue with that.[245]

[244] Tabak TI, *supra* note 83, at 95-97.
[245] Baric TI, *supra* note 39, at 181-184.

Dr. Lawrence Tabak (May 16, 2024)

Q. …Dr. Tabak, did the NIH fund the gain-of-function research at the Wuhan Institute of Virology through EcoHealth?

A. It depends on your definition of gain-of-function research. If you are speaking about the generic term, yes, we did…[246]

Dr. Baric previously stated and testified that the WIV should not have been conducting this type of research at BSL-2. This is a divergence from the beliefs of Dr. Daszak. This divergence was exemplified by the following email exchange.[247]

From: Ralph Baric [redacted]
Sent: Monday, May 10, 2021 12:21 PM
To: Peter Daszak [redacted]
Subject:

BSL2 noted in methods
J Virol. 2016 Jul 15; 90(14): 6573–6582.
Published online 2016 Jun 24. Prepublished online 2016 May 11. doi: 10.1128/JVI.03079-15
PMCID: PMC4936131; PMID: 27170748
Bat Severe Acute Respiratory Syndrome-Like Coronavirus WIV1 Encodes an Extra Accessory Protein, ORFX, Involved in Modulation of the Host Immune Response Lei-Ping Zeng,a Yu-Tao Gao,a Xing-Yi Ge,a Qian Zhang,a Cheng Peng,a Xing-Lou Yang,a Bing Tan,a Jing Chen,a Aleksei A. Chmura,b Peter Daszak,b and Zheng-Li Shicorresponding author

J Virol. 2020 Oct; 94(20): e00902-20.
Published online 2020 Sep 29. Prepublished online 2020 Jul 22. doi: 10.1128/JVI.00902-20
PMCID: PMC7527062
PMID: 32699095
Evolutionary Arms Race between Virus and Host Drives Genetic Diversity in Bat Severe Acute Respiratory Syndrome-Related Coronavirus Spike Genes Hua Guo,#a,b Bing-Jie Hu,#a Xing-Lou Yang,a Lei-Ping Zeng,a Bei Li,a Songying Ouyang,c and Zheng-Li Shicorresponding author

I think there are at least one more such paper. i'll forward letter to the editor shortly, but thought you should be informed this methodology continued into 2020.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[246] Overseeing the Overseers: A Hearing with NIH Deputy Dir., Dr. Lawrence Tabak: Hearing Before Select Subcomm. On the Coronavirus Pandemic, 118th Cong., 2, at 95-97 (May 16, 2024) [hereinafter "Tabak Hearing"].
[247] Baric TI, *supra* note 39, at 181-184.

From: Ralph Baric [redacted]
Sent: Monday, May 10, 2021 4:44 PM
To: Peter Daszak [redacted]
Subject: Re:

Hi Peter, it is true that this isn't definitive proof and I agree there is no evidence of a SARS2 like virus in their collection that is closer than RaTG13, which is still pretty distant. I also still agree that a natural origin from nature is the most likely scenario. Take care, Ralph

On Mon, May 10, 2021 at 1:57 PM Peter Daszak [redacted] wrote:

> Thanks Ralph – I'd seen those and I understand your rationale for signing the letter. I've already seen a copy – reporters are already lining up questions for me, to which I'm saying – you should contact WHO.
>
> The real issue that everyone seems to forget is whether they had a virus similar to SARS-CoV-2 in their collection. Given that we published ~650 novel RdRps (alpha and beta covs) in spring 2020, and that they were piling in every single positive they had, it just seems like a very implausible scenario. Yes, they cultured bat-CoVs at a safety level you don't, but there's no evidence anywhere that they had SARS2 or a progenitor. Journalists will write whatever they want I guess...
>
> Cheers,
>
> Peter

[redacted] SSCP00406591

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

[REMAINDER OF PAGE INTENTIONALLY BLANK]

Message

From: Ralph Baric [redacted]
Sent: 5/27/2021 7:00:34 AM
To: Peter Daszak [redacted]
Subject: Re: BSL levels for viral culture in China, US, other countries

Sorry Peter. Your being told a bunch of BS. Bsl2 w negative pressure, give me a break. There last paper mentioned bsl2 w appropriate PPE. This last part was the first and only time this was ever mentioned, never in earlier papers, and in the latest paper never defined either. I have no doubt that they followed state determined rules and did the work under bsl2. Yes china has the right to set their own policy. You believe this was appropriate containment if you want but don't expect me to believe it. Moreover, don't insult my intelligence by trying to feed me this load of BS.
Ralph

On Thu, May 27, 2021, 1:08 AM Peter Daszak [redacted] wrote:

Hi Ralph,

Hope all's well, given this ridiculous week for politics around covid origins in the news!

Since we last spoke, I've checked on a bunch of rules governing culture of viruses in the US, China and other countries. Hope you don't take this the wrong way – I'm sending you this so you're aware, and in case you get questions from reporters, and other scientists, or the govt agencies etc., not to disagree with your opinion, which I respect.

In China, the rules allow for organizations to conduct culture of animal viruses at BSL-2, including chimeras. We checked with Zhengli, who let us know that she used "BSL-2 with negative pressure and appropriate PPE". I also know that they are stricter now on SADS-CoV (it's BSL-3 I believe) ever since you showed it was able to infect human airway epithelial cells, so that's evidence they do take these things more seriously than it would seem on the surface.

I also checked the rules on a bunch of viruses for the US and was surprised to find lethal human pathogens cultured at BSL-2 (e.g. Rabies, some vector borne viruses) as well as many wildlife viruses. I also spoke with Chris Broder who let me know that the bat paramyxovirus Cedar virus (close to Nipah/Hendra) is cultured at BSL-2, including the recombinants he has made with Nipah and Hendra elements. Reference here:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5869790/

I've attached a list of some of the findings with refs. Hope it's useful in case there are questions about this. I'm sure there are reasons for all of the above classifications, and justifications that can be debated, but I just want you to know that I did the due diligence on this, and checked that they were following the rules, and that similar rules exist here. I'm sure it will be criticized, and maybe there will be tightening of biosafety levels given the hype around the lab leak hypothesis at the moment. However, I'm still very confident that nothing untoward happened there, and have good reasons for that based on the protocols they used, and the results they were sharing as we wrote a paper for Nat. Communications in the lead up to the outbreak.

Cheers,

[redacted] SSCP00406590

Peter

FINDING: EcoHealth Alliance, Inc. Submitted its Year 5 Annual Progress Report Nearly Two Years Late.

During the life cycle of a grant, the principal investigator must provide annual reports, known as RPPR, to its funding agency.[248] These reports provide the funding agency with updates on the progress of the work funded by the grant and any anticipated changes in the research approach or direction going into the next funding year. In the case of EcoHealth, these reports, especially its Year Five Report, have come under scrutiny from the NIH Office of Extramural Research and the Select Subcommittee's investigation.

EcoHealth's Year 5 Report was due September 28, 2019. However, the report was not submitted until August 3, 2021—nearly two years late.[249] This failure was first reported to Congress via an October 20, 2021 letter from Dr. Tabak to Mr. Comer.[250]

Each year, regardless of whether a grant is being evaluated for a competitive renewal, the principal investigator must submit an annual progress report. As stated above, EcoHealth's Year 5 Report—the report that included the results of research and experiments for June 2018 through May 2019, the time period immediately preceding the outbreak of the COVID-19 pandemic—was due September 28, 2019. However, EcoHealth submitted this report nearly two years later on August 3, 2021.

For project years one through four, Dr. Daszak, in addition to submitting the annual report via the NIH online reporting system, would routinely also send it via e-mail to his program officer, Dr. Stemmy. The Select Subcommittee are in possession of these e-mails for reporting years one, two, and four:

1) On May 1, 2015, Dr. Daszak emailed Dr. Stemmy the Year 1 RPPR stating, "[w]e just uploaded our Y1 Report for our Understanding the Risk of Bat Coronavirus Emergence award (1R01AI110964-01). I wanted to send you a copy of the report as well."[251]

2) On May 13, 2016, Dr. Daszak emailed Dr. Stemmy the Year 2 RPPR stating, "I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as pdf)."[252]

[248] *Research Performance Progress Report (RPPR)*, NAT'L INSTS. OF HEALTH (last updated Nov. 2, 2022) (last accessed Apr. 24, 2024).
[249] Understanding the Risk of Bat Coronavirus Emergence, RPPR (Aug. 3, 2021).
[250] Letter from Lawrence Tabak, D.D.S., Ph.D., Principal Dep. Dir., Nat'l Insts. of Health, to Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform (Oct. 20, 2021).
[251] E-Mail from Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., to Erik Stemmy, Ph.D., Program Officer, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, *et al.* (May 1, 2015) (On file with Select Subcomm. Staff).
[252] E-Mail from Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., to Erik Stemmy, Ph.D., Program Officer, Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. of Health, *et al.* (May 13, 2016) (On file with Select Subcomm. Staff).

3) On April 25, 2018, Dr. Daszak emailed Dr. Stemmy the Year 4 RPPR stating, "I just wanted to send you a pdf of our Year 4 Report which I submitted last week."[253]

When asked why he did not continue this pattern for the Year 5 Report, Dr. Daszak testified that he "wish[ed]" he did email the Year 5 Report to the NIH grants office but did not.

Dr. Peter Daszak (Nov. 13, 2023)

Q. Okay. And I think we had seen in, I think at least 1 year prior, maybe year 4, a practice of submitting the annual report through the Commons system –

A. Yeah.

Q. -- of course the way that it's submitted?

A. Yeah.

Q. And then separately from that, emailing it over to your grants office?

A. Yeah. I remember doing that a couple of times, yeah.

Q. Did that happen here?

A. No, unfortunately. I wish I'd done that. I didn't do it. You know, it's unfortunate.[254]

Dr. Stemmy was the NIAID official responsible for tracking and ensuring EcoHealth's progress reports were submitted on time. According to Dr. Stemmy, Dr. Daszak did not send an e-mail with the Year 5 Report until Dr. Daszak officially submitted it August 3, 2021.

Dr. Erik Stemmy (Nov. 13, 2023)

Q. So this is minority exhibit G. It is the year 4 progress report along with the sort of cover email from Dr. Daszak to you in April 25th, 2018. So we have this email attaching the year 4 report where he's going outside of the eRA Commons system to sort of personally hand you a copy of what he's up to. They had the big success with SADS and some other notable events.

Did he do this for year 5?

[253] E-Mail from Peter Daszak, Ph.D., EcoHealth Alliance, Inc., to Erik Stemmy, Ph.D., Program Officer, Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. of Health, *et. al*. (Apr. 25, 2018) (On file with Select Subcomm. Staff).
[254] Transcribed Interview of Peter Daszak, Ph.D., EcoHealth Alliance Inc. (Nov. 14, 2023) (hereinafter "Daszak TI").

A. I believe he sent me an email in -- contemporaneous with when he submitted the progress report in 2021, I believe that August, right? Is that when that one came in? So I believe he copied me on a message then, but not around the time that it would have been due.[255]

Dr. Daszak also testified that "the information from the Year 5 Report was in the resubmitted - - [year 6 competitive] renewal submission, in the first part of that renewal submission."[256]

Dr. Peter Daszak (Nov. 14, 2023)

Q. Could I ask –

A. But -- yeah, go ahead, go ahead.

Q. Could I ask why not, in other words, it seems as if there was a knowledge that you can always just attach the PDF to the email and send it over to Erik Stemmy.

A. Yeah.

Q. We're struggling, I think, a little bit to understand why that would not have occurred here.

A. Well, you know, one, it's me second-guessing my decisions 4 years ago, but one reason why there's less concern is, the information from the year 5 report was in the resubmitted -- the renewal submission, in the first part of that renewal submission. We had information of relevance to the work we were doing in China in that submission. So Erik Stemmy, the program officer, had seen that, without a doubt. That was part of his job to read that proposal.[257]

This sentiment was reiterated by multiple witnesses throughout the inquiry. However, after a review of the Year 6 competitive renewal, the Select Subcommittee does not believe the experiment in question in the Year 5 Report was in the renewal application. Regardless, simply because there is a renewal application, does not exempt EcoHealth from following the terms of its grant and submitting its Year 5 Report on time. As multiple NIH witnesses testified, the Year 5 Report is still due on time regardless of the competitive renewal application.

Dr. Erik Stemmy (Nov. 13, 2023)

[255] Transcribed Interview of Erik Stemmy, Ph.D., Program Officer, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, at 142 (Nov. 13, 2023) [hereinafter "Stemmy TI"].
[256] Daszak TI, *supra* note 253, at 52.
[257] *Id.*

Q. If a grant is suspended or terminated, does the prime awardee still have to complete the requirements under the grant -- administrative requirements?

HHS Counsel. If you know.

A. So my understanding is that this was a unique situation. I do recall that, when they came up for their first annual progress report, I believe the, they reached out to grants management to ask what they should submit. So I believe they still have to submit something, but, in essence, it was a paper that said, "This grant is terminated," and no action has been undertaken.

Q. No. I'm saying -- so the grant that was suspended was the renewal, the type 2, right? But they hadn't completed all the requirements on the type 1 prior to having the funding for the type 2.

A. Correct.

Q. If the type 2 is suspended, does it just waive their requirements to complete the type 1?

A. No.[258]

As an excuse for why EcoHealth's Year 5 Report was late, Dr. Daszak testified that he attempted to submit it but was "locked out" by the NIH system.

Dr. Peter Daszak (May 1, 2024)

Q. Right. I'm sorry. September 28, 2019?

A. Yes.

Q. Perfect. Thank you. But it is also true that you did not submit this report until August 2021, nearly 2 years later, as my colleague just represented.

A. Well—

Q. You did not submit the report at the end of September 2019?

[258] Stemmy TI, supra note 255, at 140-141.

A. We uploaded the report into the system. The system locked us out…[259]

This testimony does not stand up to further scrutiny. Dr. Lauer and NIH conducted a forensic audit across their systems to attempt to confirm Dr. Daszak's claim, however, NIH could not verify the claim.

Dr. Michael Lauer (Nov. 2, 2023)

Q. Okay. Oh, I meant to -- I had one other question on this late year-five report. You said earlier to somebody's questioning today that you were not convinced that EcoHealth -- EcoHealth sent a product. They had a submission. They were trying to submit it in July 2019, and they experienced a lockout. They were locked out of the eRA Commons system, and they weren't able to do it. Now, you said you were not convinced. So could you explain why you were of that view?

A. Yeah. So our office did an electronic forensic investigation of EcoHealth's encounters with our grant system, and that included both looking at activity logs. Every time that anyone interacts with our system, there is an activity log that describes when they came in, who came in, what actually happened. And it also involved our help desk ticket. So we have a help desk. And so whenever somebody calls in and says, "I am having problems with the system," that encounter that they have with our staff is recorded. We never found any evidence that they had been locked out of our system. We did see that on one day somebody from EcoHealth had attempted to log in through one -- you can log into our system in multiple different ways. And they had attempted to log in in one way and had entered the wrong password, I think, three times. And so that particular channel did get blocked. But then, on the very same day, later they were interacting with our system having logged in through a different route. And then we looked at the help desk tickets, we also looked at emails with NIAID staff, and we never saw any evidence that they claimed that they were unable to submit their progress report because the eRA system had locked them out.

Q. Okay. And if it had locked them out, weren't there other ways they could have gotten the report into NIH if they had called somebody?

A. If they were unable to submit any document because they had been locked out of the system, then what they would do is they could call

[259] A Hearing with the President of EcoHealth Alliance, Dr. Peter Daszak: Hearing Before Select Subcomm. On the Coronavirus Pandemic, 118th Cong. 2, at 23 (May 1, 2024) [hereinafter "Daszak Hearing"].

up our help desk, and then our help desk would work with them to figure out what was going on.[260]

In response to Dr. Lauer's testimony, Dr. Daszak deflected by stating that both the fact that Dr. Lauer's forensic investigation failed to find evidence supporting Dr. Daszak's claim, and his underlying claim can both be true.

Dr. Peter Daszak (Nov. 14, 2023)

Q. So I'm going to show you what's going to be majority exhibit No. 5. This is an excerpt of a transcribed interview with Dr. Lauer that the committees took earlier this month. So we asked Dr. Lauer what, as part of his compliance review of the grant, what steps he did to look into this lockout issue…So we plan to ask for that, the results of that forensic audit. But, again, wanted to get your impression as to how correct that is.

A. It's absolutely possible. What Dr. Lauer says there is true and what I'm saying to you is true. It can be true that there is, as he states, there's no evidence of us contacting the help desk and getting a help desk ticket because we maybe didn't do that. We contacted the grants officer. It can also be true that Dr. Lauer doesn't have any evidence that we'd been locked out of the system and that we were locked out of the system. Just because he can't find evidence of that doesn't mean it's not true. We were locked out of the system. Not only were we locked out of the system then, when Dr. Lauer wrote to us demanding that we immediately send the year 5 report and upload it into the system, NIH couldn't get the system to work for 11 days. We have it on record. And that's how we did keep email. So look, Dr. Lauer is a very senior manager at NIH. I'm sure that it's logical to him that someone would go to the help desk. But we had a direct point of contact in charge of grants management who never responded to us by phone. All we can do is try. And if NIH was unable to, even when they demanded the report 2 years later, they were unable to unlock the system for a number of days, it was clearly locked.

Q. Sure. I'm just giving you the opportunity to comment on his [sic]. And we don't have the forensic audit so we don't have a firm idea of the scope.

A. Well, if the forensic audit tests whether we got a help desk ticket or assesses whether we tried to log into a system or assesses whether we sent an email, then maybe the forensic audit won't find that. But

[260] Transcribed Interview of Michael Lauer, M.D., Dep. Dir., Extramural Research, Nat'l Insts. of Health, at 102-103 (Nov. 2, 2023) [hereinafter "Lauer TI"].

we tried to upload that report. We even tried when NIH told us 2 years later immediately send it and we weren't able to. The system locked us out. It's a fact.

Q. You said that you had emailed your point of contact at NIAID or NIH to try to rectify the situation, right?

A. My admin staff called the point of contact.

Q. Called?

A. I believe so, yeah. I think they emailed her, received no response, called.

Q. Because Dr. Lauer also testified that during the course of this audit they looked at emails with NIAID staff and still never saw any evidence that EcoHealth claimed you were unable to submit a progress report because the eRA system had locked them out?

A. Well, again, like I said, they may find no email evidence, but we did try to submit the report. It did lock us out. I mean, you can't get much more clearer than when NIH specifically instructed us to upload it immediately, 2-1/2 years later, in a matter of urgency, where they knew all about it and were waiting for it, they still couldn't get the system to unlock. Clearly that system needs to be fixed.[261]

The forensic analysis of the NIH reporting system concluded "[t]he user was never locked out of the system."[262] Further, the analysis determined that EcoHealth accessed the reporting system at least once a day for 72 days between July 24, 2019 and July 27, 2021.[263] The analysis stated, "[e]ach of those times accessing Commons was an opportunity to route the RPPR so it could be submitted to NIH."[264] In summary, EcoHealth could have chosen to submit its Year 5 RPPR and chose not to.[265]

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[261] Daszak TI, *supra* note 253, at 139-141.
[262] RPPR Related Activities for R01AI110964-05 and Other Actions Performed, NAT'L INSTITUTES OF HEALTH (on file with Select Subcomm. Staff).
[263] *Id.*
[264] *Id.*
[265] *Id.*.

RPPR related activities for R01AI110964-05 and other actions performed

The user was never locked out of the system:

1. eRA logs show that there was activity by PI and SO from the organization.
2. PI has a proven history of familiarity with and usage of eRA Commons, having initiated and routed 7 RPPRs during years 2015, 2016, 2017, 2018, 2019, 2021.
3. PI Initiated the Interim RPPR through the link provided on **07/24/2019** but he did not route it to the SO.
4. The day before the I-RRPR was routed by the PI to the SO (**07/26/2021**), the PI linked his account to Login.gov.
5. Then on **07/27/2021** he unsuccessfully attempted to change his eRA Commons password, and the password was locked.
6. He continues accessing eRA using Login.gov

Details:

Interim RPPR for Year 5

- R01AI110964-05 went into the systematic Closeout Process at the end of the project period.
- 06/04/2019 first email regarding documents needed for closeout was sent to the PI, the SO and the Closeout email identified by the organization in their Commons Institutional Profile.
- 07/19/2019 grant was removed from closeout and the Interim RPPR link became available systematically to both the PI and all SOs of the organization.
- **07/24/2019** - PI Initiated the Interim RPPR through the link provided.
- 05/26/2020 - PI accessed this Interim RPPR to upload a document and to enter data.
- **07/27/2021** - PI routed this Interim RPPR to SO.
- 08/02/2021 - SO uploaded documents for this Interim RPPR.
- 08/03/2021 - SO submitted this Interim RPPR to NIH.

From 7/19/2019 to 8/3/2021 the Interim RPPR link was available to access in both the PI and SOs Commons Status. Both the PI and SO accessed other applications and grants via their Commons Status, including but not limited to Just-In-Time actions and Application viewing.

During the timeframe after PI initiated the Interim RPPR through routing to the SO (07/24/2019 - 07/27/2021), the PI successfully logged into and was active in eRA systems (Commons, Commons Status, Assist) a total of 72 days. Each of those times accessing Commons was an opportunity to route the RPPR so it could be submitted to NIH.

- 12 more days in 2019 (07/25/2019, 08/05/2019, 08/16/2019, 09/10/2019, 10/02/2019, 11/08/2019, 11/18/2019, 11/21/2019, 11/22/2019, 12/03/2019, 12/05/2019, 12/06/2019)
- 38 days in 2020 (01/24/2020, 01/28/2020, 01/29/2020, 01/30/2020, 02/20/2020, 02/21/2020, 05/08/2020, 05/15/2020, 05/25/2020, 05/26/2020, 06/01/2020, 06/02/2020, 06/09/2020, 06/11/2020, 07/03/2020, 07/07/2020, 07/11/2020, 07/15/2020, 07/28/2020, 08/07/2020, 08/10/2020, 08/13/2020, 08/20/2020, 09/16/2020, 09/17/2020, 09/23/2020, 09/28/2020, 09/30/2020, 10/05/2020, 11/06/2020, 11/11/2020, 11/16/2020, 11/27/2020, 11/19/2020, 12/01/2020, 12/14/2020, 12/19/2020, 12/21/2020)
- 22 days in 2021 (03/10/2021, 03/15/2021, 03/22/2021, 03/23/2021, 03/24/2021, 03/25/2021, 03/29/2021, 03/30/2021, 03/31/2021, 04/08/2021, 04/09/2021, 04/25/2021, 05/19/2021, 05/21/2021, 05/24/2021, 06/08/2021, 06/09/2021, 06/10/2021, 06/11/2021, 06/15/2021, 07/26/2021, 07/27/2021)

PI Account details regarding "locked account"

- 07/26/2021 PI mapped their Commons account to Login.gov.
- 07/27/2021 PI was logged in with their Commons account to route the Interim RPPR to the SO and entered invalid credentials 5 times to lock their Commons password. However, before the password was locked, the PI had

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already successfully logged in, was using multiple browser windows (logs show same IP and browser) and was able to continue working in another active browser window.

- 07/28/2021 - PI logged into Commons using Login.gov and logs show continued activity through present day.

"Regenerated" Annual RPPR

- 09/16/2020 - Signing Official contacted the eRA service desk about filling out the Inclusion Enrollment data. During that call, the eRA service desk agent inadvertently regenerated the RPPR, which caused the date and list of publications to be updated.
- Grant Folder: the Annual RPPR in the eAppls section reflects the regenerated RPPR and the original RPPR is included in the eAdditions section.

Dr. Daszak, himself, publicly and via e-mail appeared to contradict his own claims that he was "locked out" from submitting the Year 5 Report on time. On October 1, 2021, Dr. Daszak wrote in an email regarding the late Year 5 Report, "[f]or your interest, here's the truth behind the mystery: We got our report ready to file for yr5 of the grant, but when it was re-funded we assumed we didn't need to…eventually NIH wrote to us and told us to file, so we did."[266]

Date: Fri, 1 Oct 2021 3:02:44 PM -0400
Sent: Fri, 1 Oct 2021 3:02:20 PM -0400
Subject: Biggest non-story yet
From: Peter Daszak <[redacted]
To: David Morens [redacted] keusch [redacted] Roberts, Rich [redacted] Robert Kessler <[redacted]; Aleksei Chmura <[redacted]
Attachments: image001.jpg; image002.jpg; image003.jpg; image004.jpg; image005.jpg; image006.jpg

If I wasn't so sick of being pilloried in the press, I would find this one amusing! These investigative reporters have found out in our pile of foia'd docs that we were late submitting a report to NIH, and managed to turn it into an innuendo filled hit job. Just awful…

https://theintercept.com/2021/10/01/nih- bat-coronavirus- grant-ecohealth-alliance/

For your interest, here's the truth behind this mystery: We got our report ready to file for yr 5 of the grant, but when it was re-funded we assumed we didn't need to. It was the first time we'd had a renewal. We then had our grant terminated by Trump and assumed we definitely wouldn't need to at that point. Eventually NIH wrote to us and told us to file, so we did.

Meanwhile, I can't believe that people like Larry Gostin are willing to be quoted in this sort of crap. I used to think he did good work, but he's repeatedly spoken out over the last few months to support Tedros and whine about our 'lack of transparency'.

Furthermore, on September 24, 2024, EcoHealth published a document [hereinafter "EcoHealth's document] that included more information regarding the Year 5 Report submission.[267] This document did not support Dr. Daszak's testimony that he was "locked out" of the NIH reporting system. In fact, this document directly contradicts Dr. Daszak's sworn testimony.

[266] E-Mail from Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., to David Morens, M.D., Senior Advisor, Nat'l Inst. Of Allergy & Infectios Diseases, *et al.,* (Oct. 1, 2021, 3:02 PM).
[267] EcoHealth Alliance, Inc., *EcoHealth Alliance Corrects the Record* (Sept. 24, 2024).

1) On page one, EcoHealth's document stated, "[e]vidence shows that EcoHealth Alliance made substantial efforts to upload its Year 5 Report, but was stymied by confusing instructions, and an NIH reporting system that had a history of substantial glitches and errors."[268]

2) On page two, EcoHealth's document stated, "[w]e provide public records of other organizations and scientists that have been locked out from submission to eRA Commons, or had difficulties uploading reports."[269]

3) On page nine, EcoHealth's document stated, "…a lack of clarification and the subsequent renewal grant award without any further request for the Year 5 report led EcoHealth to its mistaken impression that the Year 5 report was not required by NIH for its work to be in compliance."[270]

4) On page 19, EcoHealth's document included an email from NIH that informs EcoHealth, "[a]s reflected in the terms and conditions in the Notice of Award, NIH grant closeout policy requires the submission of three final reports no later than 120 calendar days after the termination of the grant. The following documents must be submitted no later than 09/28/2019."[271]

In fact, nowhere in the 139-page document does it state EcoHealth, itself, was locked out from submitting its Year 5 Report on time. None of the above statements support Dr. Daszak's testimony that EcoHealth was locked out or otherwise prevented from submitting its Year 5 Report.

Dr. Daszak also testified that, once NIH formally requested the late Year 5 Report, NIH could not open the system for 11 days.

Dr. Peter Daszak (November 14, 2023)

A. We were locked out of the system. Not only were we locked out of the system then, when Dr. Lauer wrote to us demanding that we immediately send the year 5 report and upload it into the system, NIH couldn't get the system to work for 11 days. We have it on record…[272]

A. Again we went online, and it was locked out. And we contacted NIH, and then it took something like 11 days to open up that system to allow us to submit…[273]

[268] *Id.* at 1.
[269] *Id.* at 2.
[270] *Id.* at 9.
[271] *Id.* at 19.
[272] Daszak TI, *supra* note 253, at 140.
[273] Daszak TI, *supra* note 253, at 197.

Dr. Peter Daszak (May 1, 2024)

A. But let me explain, please I if I can. NIH told us 2 years later to submit that report. It took NIH 11 days to unlock the system—so any assertion that the system was not locked are demonstrably false—11 days…[274]

Dr. Daszak's testimony is directly contradicted by NIH.

Dr. Lawrence Tabak (May 16, 2024)

Q. Thank you. When EcoHealth eventually submitted its year-5 report, Dr. Daszak testified it took 11 days to unlock the NIH system. Is this true?

A. We have no evidence of that.[275]

The fact is that Dr. Daszak was able to submit the Year 5 Report on time and he simply chose not to. This is supported by both the NIH's internal forensic analysis and Dr. Daszak's own statements.

FINDING: EcoHealth Alliance, Inc. Failed to Timely Report a Dangerous Experiment to the U.S. National Institutes of Health.

EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ."[276] As stated in the Notice of Award, "[a]cceptance of this award including the 'Terms and Conditions' is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system."[277] Even grantees that function as pass-through entities must monitor the activities of subrecipients, including foreign subrecipients, to ensure that subawards are used for authorized purposes in compliance with relevant laws and the terms and conditions of the subaward.[278]

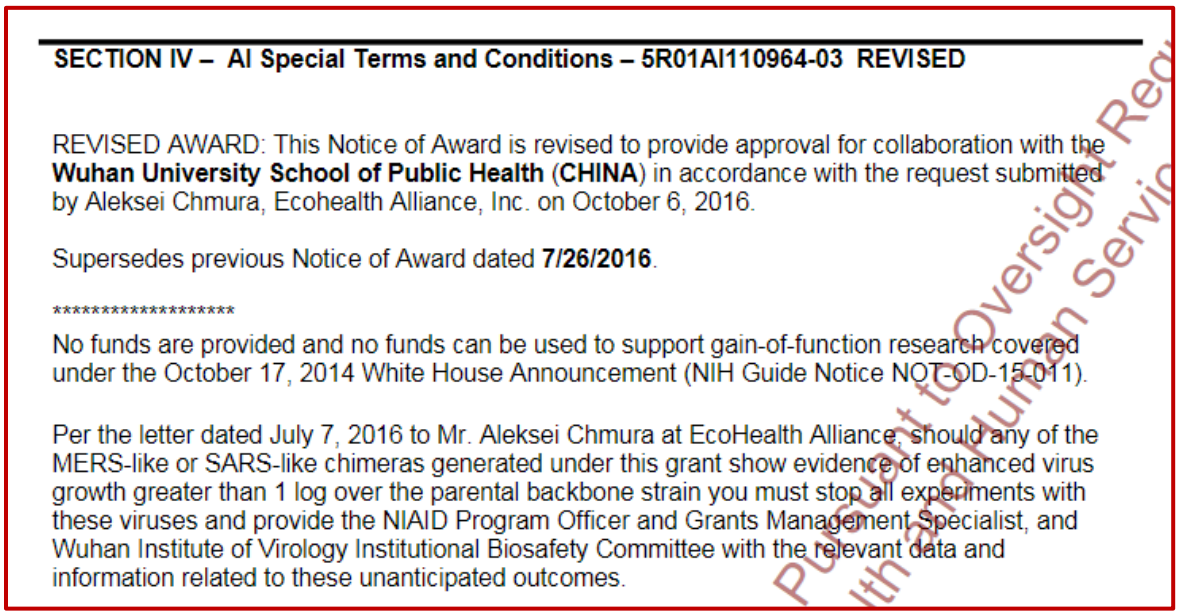
This was particularly true when NIAID identified possible gain-of-function research concerns in an experiment proposed by EcoHealth and to be conducted by the WIV. In a July 7, 2016 letter to EcoHealth, as a grantee undertaking potentially dangerous gain-of-function experiments, NIAID officials advised:

> NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater

[274] Daszak Hearing, *supra* note 259, at 25.
[275] Tabak Hearing, *supra* note 246, at 8.
[276] 45 C.F.R. § 75.352(d).
[277] NIAID, Notice of Award, EcoHealth Alliance, Grant Number 1R01A1110964-01, *Understanding the Risk of Bat Coronavirus Emergence* (May 27, 2014).
[278] 45 CFR § 75.352.

than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grant Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.[279]

This advisement was memorialized in EcoHealth's Notice of Award.



SECTION IV – AI Special Terms and Conditions – 5R01AI110964-03 REVISED

REVISED AWARD: This Notice of Award is revised to provide approval for collaboration with the **Wuhan University School of Public Health** (**CHINA**) in accordance with the request submitted by Aleksei Chmura, Ecohealth Alliance, Inc. on October 6, 2016.

Supersedes previous Notice of Award dated **7/26/2016**.

****

No funds are provided and no funds can be used to support gain-of-function research covered under the October 17, 2014 White House Announcement (NIH Guide Notice NOT-OD-15-011).

Per the letter dated July 7, 2016 to Mr. Aleksei Chmura at EcoHealth Alliance, should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes.

Pursuant to Oversight Req
Health & Human Servic

In Dr. Tabak's October 20, 2021 letter to Mr. Comer, he noted that an experiment published in EcoHealth's Year 5 Report exhibited greater than one log growth and should have been reported to NIAID but was not.

However, out of an abundance of caution and as an additional layer of oversight, language was included in the terms and conditions of the grant award to EcoHealth that outlined criteria for a secondary review, such as a requirement that the grantee report immediately a one log increase in growth. These measures would prompt a secondary review to determine whether the research aims should be re-evaluated or new biosafety measures should be enacted. EcoHealth failed to report this finding right away, as was required by the terms of the grant.[280]

NIH concluded that EcoHealth facilitated an experiment that was published in its Year 5 Report that violated this grant term and was not reported. EcoHealth argued that if an experiment did violate the one log notification requirement, it was previously reported in its Year 4 Report.

[279] Letter from Erik J. Stemmy, Ph.D., Program Officer, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Mr. Aleksei Chmura, Ph.D., Chief of Staff, EcoHealth Alliance, Inc. (July 7, 2016).
[280] Letter from Lawrence A. Tabak, D.D.S., Ph.D., Principal Dep. Dir., Nat'l Insts. of Health, to Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform (Oct. 20, 2021).

This argument is contested by NIH. Regardless, the grant term required "immediate notification", and witness testimony confirms that notification should occur within one or two business days and that simply adding the experiment to an annual report does not satisfy that requirement.[281]

As stated, whether the experiment in question occurred during Year 4 or Year 5 is a matter of dispute between EcoHealth and NIH. After reviewing the experiment, NIH determined it believed there are two separate experiments.

Dr. Erik Stemmy (Nov. 13, 2023)

Q. …That all seems, I think, consistent with what you're describing, which is, at this point, which is after the submission of the year 4 report, neither the NIAID side of things nor it sounds like Dr. Daszak understood the one log rule to have been previously implicated. In other words, you all sort of were on the same page that year 4 report did not show growth greater than one log. Is that right?

A. Yes. That's my best recollection, yes.[282]

Dr. Lawrence Tabak (Jan. 5, 2024)

Q. It says in the fourth paragraph, the first sentence, "The limited experiment described in the final progress report provided by EcoHealth Alliance...." Is it your understanding or recollection that the experiment in year 5 was different from the experiment in year 4?

A. That was our conclusion.

Q. Okay.

A. That was our conclusion. Yes.[283]

Dr. Lawrence Tabak (May 16, 2024)

Q. OK. I appreciate that clarification. So, going back to that, whether it was conducted in Year 4 or 5 of that grant, what is NIH's determination? Did it occur in Year 4 or 5?

[281] Stemmy TI, *supra* note 255, at 73-743; Transcribed Interview of Emily Erbelding, M.D., M.P.H., Dir., Division of Microbiology and Infectious Diseases, Nat'l Inst. of Allergy & Infectious Diseases, at 102-103 (Nov. 28, 2023) [hereinafter "Erbelding TI"].
[282] Stemmy TI, *supra* note 255, at 106.
[283] Tabak TI, *supra* note 83, at 81.

A. It was our evaluation that it occurred in Year 5, but because of the uncertainty, we asked for the original metadata, that is the electronic records, and the actual lab notebooks, that would have memorialized the actual events. And as you know, we never received those.

Further, Dr. Baric testified that he believed this to be two separate experiments and should have been reported to NIAID.

Dr. Ralph Baric (Jan. 22, 2024)

Q. Dr. Baric, you've read the year 5 paragraph now, the in vivo infection where five of the seven mice infected with just the WIV1 backbone survived, but only two of the eight mice infected with the WIV1 SHC014.

A. You should be able to do the statistics on that, and it should show that there's a statistical difference, which means there was an increase in virulence and the entire review process would have been triggered.

Q. So that's --

A. I think, if you did the statistics on those numbers.

Q. That's my question, is that this wouldn't have triggered P3 because it's not a human virus.

A. It doesn't matter whether it triggered P3 or not. It triggered the regulation that they agreed to in the document to follow.[284]

To support Dr. Daszak's claim that the Year 4 and 5 experiments were the same, he called Dr. Shi who assured him.

Dr. Peter Daszak (Nov. 14, 2023)

Q. This is 2021. We've had a year of all this controversy. We've had the grant canceled. We've had President Trump making his statements, Senator Cotton making his statements. And you just have this -- you have like a standing -- maybe not a standing call, but a call with the WIV, and you ask them, "One experiment or two?" "One." "I thought so. It seems like that was the case." And there was no further follow-up?

[284] Baric TI, *supra* note 39, at 181-182.

A. Correct.[285]

On Oct 23, 2021, at 00:56, Peter Daszak [redacted] wrote:

Just wanted to give you some very good news from China just now.

We've checked with Wuhan and they only did the one experiment on humanized mice. It was done during year 4 of our grant and we reported initial results from this as soon as we received them back in 2019. They didn't do viral titers, just genome copies, and we reported lung tissue data and weight loss data. The figure in the year 5 report (filed in 2021 due to grant termination etc) is from the same experiment – it's simply the follow-up histopath and survival data from that same group of mice – all done under BSL3, and all permitted by NIH. I suspected as much today because the pattern is the same for all outcomes: Genome copies per gram in lung and brain, weight loss and survival all increase more rapidly in the chimera SHC014, but level off to insignificant differences by the end of the experiment.

This is good news because it means NIH's assumption that we failed to comply with timely reporting is dead wrong, and we can push back directly to Michael Lauer in our letter about both the timing of our reporting, and about the substance of it on that issue of titers vs. genome copies, and the fact that all variables had equalized by Day 6-8 of the expt.

Breathing a slight sigh of relief here. We'll still be pilloried in the press until this new information comes out, but it gives us a chance for strong but diplomatic pushback that can then be shared with reporters at some point next week…

Dr. Daszak also confirmed that the experiment in question, regardless of when it occurred, did result in a chimeric virus that grew more than one log faster.[286]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[285] Daszak TI, *supra* note 253, at 146.
[286] E-Mail from Dr. Peter Daszak, Ph.D., President, EcoHealth Alliance Inc., to David Morens, M.D., Senior Advisor, Nat'l Inst. Of Allergy & Infectious Diseases (Oct. 20, 2021, 8:14 PM).

Date:	Wed, 20 Oct 2021 8:14:29 PM -0400
Sent:	Wed, 20 Oct 2021 8:13:08 PM -0400
Subject:	NIH is now accusing me publicly of not following GoF rules; Republicans are saying we lied to NIH
From:	Peter Daszak [redacted]
To:	Keusch, Gerald T [redacted] David Morens [redacted]
CC:	Aleksei Chmura [redacted]
Attachments:	NIH_NOA_5R01AI110964-03.PDF; NIH letter to James Comer Oct 20th 2021.jfif; NIH letter to James Comer Oct 20th 2021 2nd page.jfif; Year 4 NIAID CoV Report.pdf; To EcoHealth 10 13 21 R01AI110964 10 20 21.pdf

I need some help and advice here, and it's complicated.

In year 3 of our NIAID grant, we were given the go-ahead to conduct experiments with chimeric viruses based on SARSr and MERSr backbones, but with a proviso that:
"Per the letter dated July 7, 2016 to Mr. Aleksei Chmura at EcoHealth Alliance, should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes."
That text is in the NoA pdf attached NIH-NOA_5401AI110964-03.PDF

We asked WIV for a report on the year's work during year 4, and put a graph of an experiment they did where one of the chimeric viruses *did* grow a more than 1 log faster, but by day 4, the parental strain had leveled this out. We heard about this after the fact, and reported it in our end-of-year report. No one said anything about it at NIH until now.

NIH was FoIA'd for all documents on our original China grant, including this, and a Congressional member James Comer has asked them to explain, I think. NIH have now responded to him (and he's made the letter public) – see two image files "NIH letter to James Comer Oct 20th 2021". These are from Lawrence Tabak, and they state that we "failed to report this finding right away, as was required". They've now written to us with 5 days notice to send them the IACUC and all unpublished data. They state this in the letter to James Comer as a way of saying they're calling us to task, but it seems like nothing to do with the experiments anyway.

My problem is that James Comer is now saying EcoHealth hid GoF work from NIH.

Cheers,

Peter

Peter Daszak
President

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USA

Tel.: +1-212-380-4474
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

Dr. Tabak testified that simply calling Dr. Shi to "verify" when the experiment occurred is not sufficient and that production of the underlying data and lab notebooks was necessary and required.

Dr. Lawrence Tabak (May 16, 2024)

Q. Thank you. Dr. Daszak wrote in an email that he "verified" this experiment by calling Dr. Shi at the Wuhan Institute of Virology and asking her. Is that alone sufficient to meet his requirement to oversee subgrantees?

A. It is not, sir, which is why we asked to see the metadata, electronic records, and the laboratory notebook.

Q. [Would] the lab notebooks that Dr. Daszak failed to produce, provide information that may potentially validate this experiment?

A. I certainly hoped they would, yes.[287]

Without verifiable evidence—such as what may be in the NIH requested laboratory notebooks that Dr. Daszak has failed to provide—Dr. Daszak's claim lacks credibility.

FINDING: EcoHealth Alliance, Inc. Failed to Provide National Institutes of Health with Research the U.S. Taxpayer Funded.

On November 5, 2021, Dr. Lauer requested Dr. Daszak produce "original laboratory notebook entries" to verify certain experiments and determine if those experiments violated EcoHealth's grant terms and conditions—specifically the condition requiring notification to NIH of any experiment that exhibits excessive growth.[288]

Dr. Daszak testified that he was not required to have access to or produce the underlying original lab notebooks.

Dr. Peter Daszak (November 14, 2023)

Q. …Pursuant to these regulations did EcoHealth get the lab notebooks and the lab electronic files at the time the human mice experiment were conducted in 2017 to 2018, and reported it in the year 4 progress report?

A. No, we did not. Had we got those reports, we would have submitted them to NIH when requested[.]

[287] Tabak Hearing, *supra* note 246, at 8-9.
[288] Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Peter Daszak, Ph.D., Pres., EcoHealth Alliance, Inc. (Nov. 5, 2021).

Q. So I guess my question then is, why didn't you send off the alarm bells that something wasn't right, that we weren't getting the data that we were contractually obligated to get?

A. No, no, no. We definitely got the data we were contractually obligated to get, which is the results of the experiments. There is no contractual obligation at that time that a grantee should get the lab notebooks. That's a very different thing[.]

Q. It's in the regulations as part of what you're operating under.

A. No. I understand your interpretation of regulations, but my interpretation, our administrative team, at the time, the regulations were not considered by any organization that you should get all the lab notebooks. And I want to point out that NIH has now made it a new rule to get hold lab notebooks to clarify what is clearly not obvious in the codes and regulations.[289]

However, according to witnesses, EcoHealth should have had and was required to have access to these notebooks.

Dr. Emily Erbelding (Nov 28, 2023)

Q. Thank you. Yes. That's what I was asking. When Dr. Lauer -- he's asked for the notebooks a couple times. We've already discussed EcoHealth hasn't produced them. And it is EcoHealth's responsibility to produce them when requested. Is that correct?

A. [Nonverbal response.]

Q. You have to give an audible answer.

A. Yes. Oh, I'm sorry. Yes.[290]

Dr. Michael Lauer (Nov. 2, 2023)

Q. And, in your opinion, NIH had the authority to ask for those notebooks and files?

A. Yes.

[289] Daszak TI, *supra* note 253, at 77-78.
[290] Erbelding TI, *supra* note 281, at 101.

Q. And, in your opinion, EcoHealth should've had access to those notebooks and files?

A. Yes.[291]

Dr. Lawrence Tabak (Jan. 5, 2024)

Q. So, at the time of the EcoHealth enforcement actions, it would have been a requirement, if NIH requested lab notebooks, for EcoHealth to provide them?

A. Yes, it would've been.[292]

Dr. Lawrence Tabak (May 16, 2024)

Q. Dr. Tabak, when the National Institute[s] of Health requested the notebooks from EcoHealth, was EcoHealth required to produce them under its grant's terms?

A. Yes, they were.

Q. OK. Thank you. When NIH requested notebooks from EcoHealth, should EcoHealth have been able to access them or already have access them?

A. That is correct.

Q. OK. Thank you. Did EcoHealth ever produce the requested notebooks?

A. They have not.

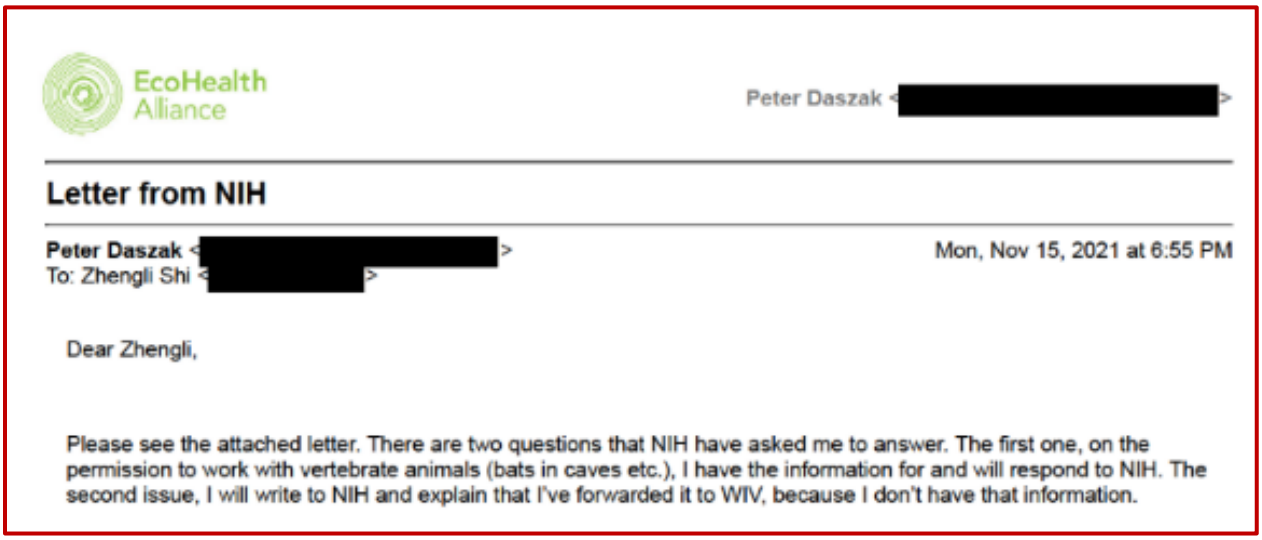
Q. Never did. Thank you. Dr. Daszak testified 2 weeks ago that he was not required to produce the lab notebooks. Would NIH disagree with that testimony?

A. Yes, we disagree with that testimony.

On November 18, 2021, Dr. Daszak said that, despite the requirement to do so, he does not have access to the requested laboratory notebooks. Specifically, Dr. Daszak stated, "[w]e do not have copies of these, which were created by and retained by the WIV. Nonetheless, I have forwarded your letter to the WIV, and will let you know their response soon as the WIV replies

[291] Lauer TI, *supra* note 260, at 74.
[292] Tabak TI, *supra* note 83, at 100.

to our request."[293] It appears Dr. Daszak never explicitly requested the notebooks from the WIV, but instead simply informed it of the request from NIH.



EcoHealth Alliance

Peter Daszak <[redacted]>

Letter from NIH

Peter Daszak <[redacted]> Mon, Nov 15, 2021 at 6:55 PM
To: Zhengli Shi <[redacted]>

Dear Zhengli,

Please see the attached letter. There are two questions that NIH have asked me to answer. The first one, on the permission to work with vertebrate animals (bats in caves etc.), I have the information for and will respond to NIH. The second issue, I will write to NIH and explain that I've forwarded it to WIV, because I don't have that information.

On April 26, 2024, NIH followed-up and asked EcoHealth for more information regarding its efforts to recover the laboratory notebooks.[294]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[293] Letter from Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., to Michael Lauer, M.D., Dep. Dir. Extramural Research, Nat'l Insts. of Health (Nov. 18, 2021).
[294] Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Peter Daszak, Ph.D., President, EcoHealth Alliance Inc. (Apr. 26, 2024).

Here's the brunt of Lauer's email:

By the way – we just received a response from Michael Lauer re. the lab notebooks. We voluntarily shared the email from us to WIV that the SSCP has asked for, that shows we forwarded NIH's demand for us to get WIV's notebooks. As is typical for Lauer, rather than say 'thanks' and move on, he's come back with further questions and demands, written in the style of a suspicious NKVD operative under Stalin. He knows these will be foiad at some point, and has written them in a way that once again implies we're either hiding information or didn't' fully comply with their request 2 yrs ago. They're also designed to make a point – if we are still communicating with WIV (which we have to if we're going to publish papers from our prior work), why aren't we demanding the notebooks? This, even though NIH has specifically told us no work in China, and HHS has debarred them from federal funding. It's a massive overreach from NIH and more like the sort of work a CIA operative would do…

Dear Dr. Chmura,

Thank you for your response. We have some follow-up questions:

- When you (EHA) received no response from WIV, did you follow-up with WIV to confirm receipt of the email, or did you otherwise follow-up with them after not hearing back?
- Did you communicate with or attempt to communicate with WIV after NIH sent a follow-up letter in January 2022 (3rd attachment)?
- Did you ever explicitly request that WIV send the lab notebooks and electronic files to you? All we see is that you forwarded the NIH email to WIV and stated, "I will write to NIH and explain that I've forwarded it to WIV, because I don't have that information."
- Were there any other EHA communications with WIV during the period of November 15, 2021, and February 1, 2022?

Sincerely,
Michael S Lauer, MD

Dr. Daszak's responses to NIH indicate that the WIV did receive the request for lab notebooks—but ignored it, EcoHealth did not follow up and re-request the lab notebooks, and that communications between EcoHealth and the WIV were allegedly "strained."[295]

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[295] Letter from Peter Daszak, Ph.D., President, EcoHealth Alliance Inc., to Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health (Apr. 26, 2024).

Message

From: Peter Daszak [redacted]
Sent: 5/10/2024 1:15:44 PM
To: [redacted] Jeff Sturchio [redacted] Aleksei Chmura [redacted]
Subject: What we sent to NIH re. contacting WIV for their lab notebooks
Attachments: EcoHealth Alliance - Letter to NIH re Grant Suspension 8-13-2020 (with Exhibits).pdf; To EcoHealth R01AI110964 11 5 21 clean.pdf; January 2022 To EcoHealth R01AI110964 final.pdf; Response to NIH April 2021 re. reactivation and suspension of 2R01AI110964.pdf; EHA to WIV Lab Notebook Email (1).pdf; To EHA document request 4 12 24[94].pdf

Importance: High

[redacted]

Re. Jeff's earlier email. In early April, after the SSCP made public the letter of them asking us for further information we got an email from Michael Lauer of NIH asking us to share with them everything we were going to send to the SSCP re. questions about our handing over of the lab notebooks from WIV. There was just one email – me forwarding the letter to WIV with NIH's demand for us to acquire their lab notebooks and hand them over. We did contact them ahead of that and let them know that the email would be coming and what it was about.

Of course, as usual, Lauer came back with more questions, which we carefully answered below, with Jeff's help. I can't remember if we ran this by you – there was a lot on and he upped the ante yesterday by emailing again, demanding a faster response.

Please read what we sent so you're aware. It's all true, and I'm fairly certain does not provide anyone any evidence of any willful negligence, violation of CFRs etc. but of course, it's all about public show and Lauer's email is written in a 'breathless' way designed to imply we're stonewalling.

Final point is that we might get another letter by COB today from Michael Lauer requesting us to provide detailed information to all the points that the SSCP has asked Tabak. That would put us in a difficult position – tipping our hand to the people who are willing to throw us under the bus. I'll let you know if one emerges.

Cheers,

Peter

Peter Daszak
President

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USA

Tel.: +1-212-380-4474

Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Aleksei Chmura [redacted]
Sent: Thursday, May 9, 2024 12:03 PM
To: Jeff Sturchio [redacted]
Cc: Peter Daszak [redacted]
Subject: Fwd: REPLY REQUESTED -- Re: Re: Time sensitive document request from NIH

Begin forwarded message:

From: Aleksei Chmura [redacted]
Subject: REPLY REQUESTED -- Re: Re: Time sensitive document request from NIH
Date: May 9, 2024 at 11:51:07 EDT
To: "Lauer, Michael (NIH/OD) [E]" [redacted]
Cc: "Liza (NIH/OD) [E] Bundesen" [redacted] "Bulls, Michelle G. (NIH/OD) [E]" [redacted] "Ta, Kristin (NIH/OD) [E]" [redacted] Peter Daszak [redacted] Alison Andre <[redacted]

Dr. Lauer,

Thank you for your email of April 26th. We have answered your questions below.

However, first we would like to remind you that in April 2020, you wrote to EcoHealth Alliance with questions about WIV's current status on R01 AI110964. We informed you that we did not have an active contract with the WIV and would not execute one until further instructions from NIH. You then terminated our grant at the behest of President Trump. You then reinstated and instantly suspended in July 2020 with a number of conditions that were impossible to address in the middle of a pandemic, and with COVID-19 origins allegations causing a political storm between the USA and China, specifically around issues related to the WIV. In your 'reactivation and suspension' letter of July 2020, you instructed us that "Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted." The communication from NIH to EcoHealth Alliance in November 2021 requesting the WIV lab notebooks was therefore sent during a time when we had no contractual obligation with the WIV, and when the WIV had been non-responsive to multiple journalist requests on similar issues, and did not comply with direct requests for their audits made by Dr. Daszak as part of the WHO mission to Wuhan in January and February 2021 (see attached 11 April 2021 letter that Dr. Daszak sent to you detailing the requests that he made to the WIV during the WHO mission). It's also important to remember that public reporting prior to our request to WIV included NIH Director Dr. Collins' comments about NIH wanting to see the lab notebooks (https://www.cnbc.com/2021/08/23/covid-origin-nih-director-doesnt-rule-out-that-virus-could-have-leaked-from-lab.html) and there were already stories in the press (e.g. https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/) clearly indicating that the US intelligence agencies were investigating allegations that WIV was the source of a lab leak that led to COVID-19. Therefore it is not unreasonable to conclude that any request for WIV's lab notebooks, whether from a non-profit, or a US agency, would be dealt with at the highest political levels within China, and given the pattern of prior responses, ignored.

Despite these difficulties, and our lack of a formal business relationship with the WIV, EcoHealth Alliance made a good faith effort to obtain the lab notebooks. We were, not surprisingly, unsuccessful. This was part of a

pattern of non-responsiveness from Chinese institutions on issues of political tension, and in particular on COVID origins, which culminated in the debarment letters sent by HHS to Wuhan via UPS being 'returned to sender'. It is unreasonable, therefore to expect a US-based non-profit to get a response on this issue where a US government agency was unable to.

Your request then, and your questions now, put our staff in an unfortunate position. We owe a duty to the American people to get the best value for the taxpayer funding that we used to collect thousands of samples in China, and for the scientific research we did in collaboration with the WIV. We have therefore continued to keep the scientific channels with collaborators in China open to the best of our ability, allowing us to analyze data, finish scientific manuscripts, and upload sequences into the US NIH Genbank database – without any further expenditure of US taxpayer funds. While communication is difficult, we have been able to do that successfully and we hope that you agree that securing the data and publishing them in the peer-reviewed literature is a worthy goal consistent with the objectives of our R01 grant from the NIH.

We have responded to your questions below, to the best of our ability.

Sincerely,

- Dr. Chmura

Aleksei Chmura, PhD, MBA
Chief of Staff &
Authorized Organizational Representative

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

1. When you (EHA) received no response from WIV, did you follow-up with WIV to confirm receipt of the email, or did you otherwise follow-up with them after not hearing back?
We were informed that they had received our email. This was communicated to us by phone.

2. Did you communicate with or attempt to communicate with WIV after NIH sent a follow-up letter in January 2022 (3rd attachment)?
Your letter of January 2022 stated that "We [NIH] are following up to confirm whether you received a response from WIV and whether the materials are forthcoming." It also asked that "Upon receipt of this letter, please confirm whether you have received a response from WIV and whether the materials are forthcoming. If the materials are forthcoming, we request that they be provided to us no later than close-of-business on January 14, 2022." We had received no response from the WIV at that time (nor have we since) regarding the lab notebooks, and informed you of that rapidly. We did not send further communications to the WIV to request the laboratory notebooks, since it seemed to us that their lack of a response was a clear indication that our efforts would have been futile, and because it was also in keeping with their prior lack of response to media, WHO or US agency requests, and also that NIH or HHS would have been able to take this up directly with the WIV or the Chinese Government at a higher level.

3. Did you ever explicitly request that WIV send the lab notebooks and electronic files to you? All we see is that you forwarded the NIH email to WIV and stated, "I will write to NIH and explain that I've forwarded it to WIV, because I don't have that information."
Yes, we informed WIV by phone ahead of our email request to make sure they understood the nature of the letter and what was required of them by NIH. We then sent the letter by email, as we shared with you and the SSCP. The letter is crystal clear in its request from NIH that WIV supply the lab notebooks (your letter is attached). Additionally, it is commonsense that WIV were fully aware of the contents of that request – it was international news at the time.

4. Were there any other EHA communications with WIV during the period of November 15, 2021, and February 1, 2022?
Communications were extremely strained at that time. Our search of emails reveals none directly related to this issue – in keeping with our understanding that the WIV were not willing to hand over lab notebooks. The only other communications represented our staff trying to obtain information to finalize research papers related to earlier work from R01 AI110964 and other publication issues.

From: Lauer, Michael (NIH/OD) [E] [redacted]
Date: Friday, April 26, 2024 at 5:00 AM
To: Aleksei Chmura [redacted]
Cc: Lauer, Michael (NIH/OD) [E] <[redacted], Bundesen, Liza (NIH/OD) [E] [redacted] Bulls, Michelle G. (NIH/OD) [E] [redacted], Ta, Kristin (NIH/OD) [E] [redacted]
Subject: Re: Time sensitive document request from NIH

Dear Dr. Chmura,

Thank you for your response. We have some follow-up questions:

1. When you (EHA) received no response from WIV, did you follow-up with WIV to confirm receipt of the email, or did you otherwise follow-up with them after not hearing back?
2. Did you communicate with or attempt to communicate with WIV after NIH sent a follow-up letter in January 2022 (3rd attachment)?
3. Did you ever explicitly request that WIV send the lab notebooks and electronic files to you? All we see is that you forwarded the NIH email to WIV and stated, "I will write to NIH and explain that I've forwarded it to WIV, because I don't have that information."
4. Were there any other EHA communications with WIV during the period of November 15, 2021, and February 1, 2022?

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Director, NIH Office of Extramural Research
1 Center Drive, Room 144, Bethesda MD 20892
[redacted]

From: Aleksei Chmura [redacted]
Date: Tuesday, April 23, 2024 at 1:45 PM
To: Lauer, Michael (NIH/OD) [E] [redacted]
Cc: Bundesen, Liza (NIH/OD) [E] [redacted], Peter Daszak [redacted] Bulls, Michelle G. (NIH/OD) [E] [redacted], Ta, Kristin (NIH/OD) [E] [redacted], Alison Andre [redacted]
Subject: Re: Time sensitive document request from NIH

Dear Dr. Lauer,

The Select Subcommittee on the Coronavirus Pandemic (SSCP) and the Committee on Energy and Commerce requested item on page 6, a.iii referenced in your letter from the 12th of April, asked for "Documents and communications regarding EcoHealth's efforts to obtain WIV laboratory notebooks pursuant to NIH oversight and compliance efforts". On the SSCP deadline of the 18th, EcoHealth Alliance provided the following file:

https://www.dropbox.com/scl/fi/1dcp5jkv0mvvola6mpakb/EHA-to-WIV-Lab-Notebook-Email.pdf?rlkey=lyizyigddayu7syidgedjv11c&dl=0

This file is an email in which EcoHealth Alliance conveyed NIH's request for the Wuhan Institute of Virology laboratory notebooks. EcoHealth Alliance received no response from Wuhan Institute of Virology at the time, nor has it ever received any response, nor ever seen the requested laboratory notebooks.

Sincerely,

-Dr. Chmura

Aleksei Chmura, PhD, MBA
Chief of Staff &
Authorized Organizational Representative

EcoHealth Alliance
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New York, NY 10018-4182

www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

On Apr 12, 2024, at 16:00, Lauer, Michael (NIH/OD) [E] [redacted] wrote:

Dear Dr. Chmura,

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Director, NIH Office of Extramural Research
1 Center Drive, Room 144, Bethesda MD 20892
Michael.Lauer@nih.gov

EcoHealth's document contended that "[a]t the time of NIH's request for WIV lab notebooks from EcoHealth Alliance, there was no specific requirement for NIH grantees to require foreign subrecipients to provide laboratory notebooks and other raw data."[296] This statement is disputed by NIH.

Dr. Lawrence Tabak (November 14, 2024)

Q. Okay. Thank you. One final question for you. Dr. Daszak has routinely said that the regulations did not require that he provide NIH with lab notebooks from the Wuhan Institute of Virology. Last year, NIH put out a new rule regarding this issue. So, just to clarify, when NIH asked for these lab notebooks, was Dr. Daszak required to produce them?

A. He was indeed.[297]

According to Dr. Daszak's consultant, Dr. Sturchio, they agreed that pursuant to regulations "NIH has the right to review original lab notebooks and data, and that EHA would in the normal course of events be able to obtain these data from the WIV."[298]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[296] *Executive Summary: EcoHealth Alliance responses to recent allegations from the SSCP*, ECOHEALTH ALLIANCE, INC., available at https://www.ecohealthalliance.org/wp-content/uploads/2024/09/EcoHealth-Alliance-Responses-to-Questions-from-SSCP.pdf.
[297] Preparing for the Next Pandemic, *supra* note 230, at 20.
[298] E-Mail from Jeffrey Sturchio, Ph.D. Consultant, Peter Daszak, Ph.D., EcoHealth Alliance Inc., *et al.* (Jan. 17, 2022, 10:40).

Message

From: Jeffrey Sturchio [redacted]
Sent: 1/17/2022 10:40:04 PM
To: Peter Daszak [redacted]; Keusch, Gerald T [redacted]
CC: Aleksei Chmura [chmura@ecohealthalliance.org]
Subject: RE: Draft response to the first of the two letters from NIH

Peter: I think the response is a good draft. Let's spend some time refining and tightening the argument. On issue 1, the IACUC approval, Lauer continues to move the goalposts on you. In his initial letter, he asked for the WIV IACUC approval for field work, which you quite rightly pointed out is not required by Chinese regulations, so there is no WIV IACUC approval for field work. He then dings you for non-compliance for not sending him the information about the Tufts IACUC approval – when it was available in the NIH system all along. This is at most a misunderstanding, and seems to me hard to construe as non-compliance with NIH regulations.

Issue 2 is a bit more complicated, as you appreciate, but I think we can boil it down to the following. Yes, there is CFR language that NIH has the right to review original lab notebooks and data, and that EHA would in the normal course of events be able to obtain these data from the WIV. But his pedantic insistence on these rules completely ignores the context of his request – the NIH unilaterally suspended your relationship with the WIV for political reasons in April 2020 and thus your usual interactions with WIV collaborators were abrogated through no fault of EHA's. Since that decision by the NIH – due to White House political pressure stemming from the then President's fraught relationship with China – the situation surrounding this grant was disrupted in a unique way. It is disingenuous, to say the least, for Lauer to now demand that you turn over WIV's laboratory notebooks and related data, when the actions of NIH and the USG have made it impossible for you to maintain the usual kind of relationship with your Chinese collaborators on which that exchange of data would usually be based. Under the circumstances, you have taken the appropriate action – asking the WIV to provide the data, which is under their control. If Lauer feels it is so important to see the original data, it is unreasonable of him to expect EHA to be able to provide it, given the political context of this grant; under these circumstances, he should use NIH intergovernmental channels to gain access to the data. That kind of cooperative action would be more appropriate than the confrontational approach he is taking.

As ever,
Jeff

In addition to Dr. Daszak arguing that he was not required to provide the laboratory notebooks to NIH, he also stated "[t]he geopolitical tensions with China regarding COVID-19 made NIH's requests effectively impossible for EcoHealth Alliance to fulfill."[299] Despite this

[299] *Executive Summary: EcoHealth Alliance responses to recent allegations from the SSCP*, ECOHEALTH ALLIANCE, INC., *available at* https://www.ecohealthalliance.org/wp-content/uploads/2024/09/EcoHealth-Alliance-Responses-to-Questions-from-SSCP.pdf.

claim, Dr. Daszak and Dr. Shi maintained a friendly relationship, even discussing the Select Subcommittee's hearings via email.[300]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[300] E-Mail from Peter Daszak, Ph.D., EcoHealth Alliance, Inc., to Shi Zhengli, Ph.D., Wuhan Institute of Virology (Apr. 29, 2024, 7:44 AM); E-Mail from Shi Zhengli, Ph.D., Wuhan Institute of Virology, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc. (Apr 28, 2024, 11:50 PM); E-Mail from Peter Daszak, Ph.D., EcoHealth Alliance, Inc., to Shi Zhengli, Ph.D., Wuhan Institute of Virology (Apr. 15, 2024, 5:48 AM); E-Mail from Shi Zhengli, Ph.D., Wuhan Institute of Virology, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc. (Apr 11, 2024, 10:39 PM);

From: 石正丽 [redacted]
Sent: 4/29/2024 8:37:37 PM
To: Peter Daszak [redacted]
CC: Hongying Li [redacted]
Subject: Re: RE: RE: RE: SADS-CoV analysis

Importance: High

Received, thanks.

-----原始邮件-----
发件人:"Peter Daszak" [redacted]
发送时间:2024-04-30 01:14:25 (星期二)
收件人: "石正丽" [redacted]
抄送: "Hongying Li" [redacted]
主题: RE: RE: RE: SADS-CoV analysis

Here's the paper as promised!

Cc'ing Hongying so she can make sure you get the attachment if this one doesn't work.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
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New York, NY 10018-6507
USA

Tel.: +1-212-380-4474
Website: www.ecohealthalliance.org

EHA_0003630

Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: 石正丽 <[redacted]>
Sent: Sunday, April 28, 2024 11:50 PM
To: Peter Daszak <[redacted]>
Subject: Re: RE: RE: SADS-CoV analysis

Dear Peter, I fully support you! I'll try to connect the hearing and I believe you will beat them down. Shame those stupid politicians!

-----原始邮件-----
发件人:"Peter Daszak" <[redacted]>
发送时间:2024-04-29 07:44:49 (星期一)
收件人: "石正丽" <[redacted]>
抄送:
主题: RE: RE: SADS-CoV analysis

Thanks for your positive message that I just noticed Zhengli. Yes, it's pretty horrible that it's now 4 years and 4 days since President Trump canceled out grant, and we're still being attacked. In these past 4 years, we've had over 100 Freedom-of-Information-Act requests, where people go through your emails and make them public in nasty news articles. We've had 8 lawsuits trying to claim we caused COVID and people's deaths. We've had multiple Government committees doing 'investigations', as well as the OIG for the HHS (NIH) and USAID. We estimate we've produced around 15 million pages of emails/documents/financial data for these investigations.

Worse still, we're still being harassed by Michael Lauer, the person at NIH who attacked Chinese Americans, many of whom had innocent connections to China but had to lose their jobs https://www.science.org/content/article/pall-suspicion-nihs-secretive-china-initiative-destroyed-scores-academic-careers. He's effectively preventing EcoHealth from working internationally and on animal research. We've had over 50 official letters from NIH and all of them ask us to do more work and produce more detailed documents, but still they're holding us back. I hope it will end soon.

Here is a link to the public hearing on May 1st 10am Washington DC time (10pm your time I think). It's worth listening to my opening statement that will be in the first hour, where I'll give a summary of how important our work is, and how wrong these 'rumors' are...

WHAT: Hearing titled "A Hearing with the President of EcoHealth Alliance, Dr. Peter Daszak"

DATE: Wednesday, May 1, 2024

TIME: 10:00AM ET

LOCATION: 2154 Rayburn House Office Building

WITNESS:

EHA_0003631

Dr. Peter Daszak

President

EcoHealth Alliance, Inc.

WATCH: The hearing will be open to the public and press and will be livestreamed online at https://oversight.house.gov/hearing/a-hearing-with-the-president-of-ecohealth-alliance-dr-peter-daszak/.

By the way – I'll be sending you the SADS-CoV paper back with comments befor the end of your Monday – apologies for the delay!

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

520 Eighth Avenue, Suite 1200

New York, NY 10018-6507

USA

Tel.: +1-212-380-4474

Website: www.ecohealthalliance.org

Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: 石正丽 [redacted]>
Sent: Sunday, April 14, 2024 8:57 PM
To: Peter Daszak <[redacted]
Subject: Re: RE: SADS-CoV analysis
Importance: High

Dear Peter,

EHA_0003632

It's a shame those peoples called them as "experts" of CIVID-19 origin investigation. I've read the letter to you from the Congressional Committee. It's incredible this happed in USA, a so called "most developed and democratic" country. I believe your a public hearing with the Congressional Committee will be good opportunity to show our invaluable contribution to EID research field. I'm staying together with you!

Best regards,

Zhengli,

-----原始邮件-----

发件人:"Peter Daszak" <[redacted]>

发送时间:2024-04-15 05:48:30 (星期一)

收件人: "石正丽" <[redacted]>

抄送: "Hongying Li" <[redacted]>

主题: RE: SADS-CoV analysis

Hi Zhengli – great to see the manuscript and I would be honored to be involved as a co-author.

Give me a couple of weeks to make some comments. I hope it doesn't clash at all with the other paper which is in review at PNAS right now (I've attached that manuscript to remind you). I think it should be fine – there are many differences between the two papers, and I will read through and edit before the 28th of April.

You're right that I have to be in a public hearing with the Congressional Committee that is attacking us about COVID origins. It is on May 1st, and it will be very unpleasant, but I have no choice. My main goal will be to try to let people know the simple truth about our work and try to reduce the damage from these attacks.

Cheers,

Peter

Peter Daszak

President

EHA_0003633

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Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: 石正丽 [redacted]
Sent: Thursday, April 11, 2024 10:39 PM
To: Peter Daszak [redacted]
Subject: SADS-CoV analysis

Dear Peter,

We have completed the sequences of SADS-related CoV (or HKU2-CoV) and wrote the preliminary manuscript. I would like to invite you as a coauthor for this paper. I've not yet edited the paper and I'm sending it to you for your review at your available time. I would also like to suggest to combine the recently submitted one: "**Diversity and spillover risk of Swine Acute Diarrhea Syndrome and related coronaviruses in China and Southeast Asia**". Please let me know what do you think.

For the SARS-related CoV paper, have you had the time for the final check?

I heard that you will be in the congressional hearing in May, Is that true?

Best regards,
Zhengli,

EHA_0003634

FINDING: To Get a Grant Reinstated, EcoHealth Alliance, Inc Misled the U.S. National Institutes of Health Regarding the Physical Location of U.S. Funded Samples.

It is NIH policy to make every possible attempt to return grantees to compliant status. However, in the case of EcoHealth, NIH turned a blind eye to potential issues with the reinstatement of this grant. Evidence gathered by the Select Subcommittee suggests that Dr. Daszak omitted a material fact during the grant reinstatement process—a fact that may have changed whether EcoHealth's grant was reinstated or not.

On April 26, 2023, NIAID reinstated EcoHealth's grant.[301] On May 8, 2023, EcoHealth publicly announced this reinstatement.[302] In NIH's notification to Congress, it stated that EcoHealth had been organizing and implementing a corrective action plan to satisfy NIH's compliance efforts.[303] NIH's goal during compliance investigations is to bring the grantee back into compliance and to design a corrective action plan to support that outcome.

> **Dr. Michael Lauer (Nov. 2, 2023)**
>
> So, again, our philosophy -- and it's not just a philosophy; it's what's grounded in the uniform guidance regulations -- is that, when a recipient is out of compliance, the goal is to bring them back into compliance. And we can do that, as I said, through a variety of means -- through revising terms and conditions of award, through specific award conditions, through a corrective action plan. Because, ultimately, what we want is we want the recipient to be successful and we want them to be compliant with terms and conditions.[304]

However, in the case of EcoHealth, one of the required conditions could not be remedied. NIH requested EcoHealth provide laboratory notebooks to establish what gain-of-function experiments involving coronaviruses were conducted with U.S. taxpayer dollars at the WIV. EcoHealth failed to provide these notebooks.[305]

- However, NIH also identified one non-compliance requirement under the grant R01AI110964 (R01) that could not be remedied with SACs. NIH had requested EHA provide NIH the laboratory notebooks and original electronic files from the research conducted at WIV. Since EHA failed to provide these records and WIV was unable to fulfill its duties for the subaward, NIH notified EHA on August 19, 2022, that it would be terminating the WIV subaward for failure to meet award terms and conditions.

[301] *See,* Grant Summary, R01AI110964, USASpending (last accessed Apr. 24, 2024).
[302] *EcoHealth Alliance Receives NIH Renewal Grant for Collaborative Research to Understand the Risk of Bat Coronavirus Spillover Emergence*, ECOHEALTH ALLIANCE, INC. (May 8, 2023).
[303] Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability (Apr. 26, 2023).
[304] Lauer TI, *supra* note 260, at 80.
[305] Lauer Letter, *supra* note 303.

In a notification to EcoHealth sent on the same day, NIH wrote, "[t]he award R01AI110964 beginning on April 19, 2020, remains suspended pending the renegotiation of specific aims for the award without the involvement of the Wuhan Institute of Virology."[306] The Select Subcommittee proceeded to gather evidence regarding the rationale for the renewal. One of the primary reasons for reinstating the grant to EcoHealth was its alleged access to sequences and samples previously paid for by the federal government and not yet analyzed.

Dr. Emily Erbelding (Nov. 28, 2023)

Q. And then I want to somewhat briefly parse out a little bit more on the samples. So you referenced earlier you and Dr. Lauer provided a briefing to a number of committees over the summer on the EcoHealth Alliance reinstatement. And one of the reasons given for reinstating the grant were that there were these bat samples collected from China and Southeast Asia with funding that still needed to be tested or sequenced, or I forget the exact language that was used.

Is that correct?

A. Is it correct that I said that to the committee –

Q. Yes.

A. -- or --

Q. Is that your understanding of the grant, the reason for the grant reinstatement?

A. That was part of the reason, yes, that we wanted to get the most out of existing sequences from prior work. We wanted to get the most out of prior work.

Q. What were the other rationales?

A. Well, that they could address a scientific priority of NIAID in understanding how pandemics occur. I think that it would be -- that they had been scientifically productive in the past. That was another part of the rationale for reinstatement.

Q. If you know, at the time of reinstatement, how many samples did EcoHealth have access to that remained untested?

A. I don't know the number.

[306] Letter from Michelle Bulls, Dir., Office of Policy for Extramural Research Administration, Office of Extramural Research, Nat'l Insts. of Health, to EcoHealth Alliance, Inc. (Apr. 26, 2023).

Q. Did EcoHealth -- was it EcoHealth that told you that they had samples?

A. They did -- they did give an approximate number. I don't recall what it was.

Q. Did they tell you that the samples were in their possession?

A. I believe I asked, You have access to these samples? Do you have access to these samples? I think that, to my -- to the best of my recollection, that's how I phrased the question. And I got an affirmative answer. That was, I think, the conversation.

Q. You asked, do you have access, and they responded yes?

A. This was Peter Daszak. Yes.

Q. There wasn't an elaboration on the yes?

A. I did not ask further questions. I took his representation as truthful.[307]

Dr. Erbelding testified that, at the time of the reinstatement, NIAID believed that EcoHealth had access to sequences and samples the federal government had previously paid to have collected but that had yet to be analyzed. For reasons that are not clear to the Select Subcommittee, NIAID apparently never asked EcoHealth where the samples were located. Instead, NIAID relied solely on the representations of Dr. Daszak that the samples existed and that he had access to them. In reality, EcoHealth was relying on the WIV, an institute debarred for failing to produce laboratory notebooks, to provide them with the virus samples and sequences that were the justification for reinstatement.

Dr. Peter Daszak (Nov. 14, 2023)

Q. I have got a few quick questions on the reinstatement. And then one circle back on the intelligence community issue. So the reason you should know this, but Drs. Lauer and Erbelding gave us a congressional briefing a few months ago on the reinstatement and some of the decisions and, you know, additional terms put in place. One of the reasons -- one of scientific rationales for reinstating the grant is that there remains thousands of bat samples collected from China with funding basically paid for by the grant before it was suspended, but still need to be tested for the presence of the virus. Is that still the case?

[307] Erbelding TI, *supra* note 281, at 55-56.

A. Well, we have new data from China on some of those -- on the results from some of those samples. We are currently analyzing it. Very important critical data. And yeah, I think it's -- we're getting there. It's good to have new information, but there are still many samples that we don't have direct control over.

Q. Sure. Who is the custodian for those samples presently?

A. Right now, they are in the Wuhan Institute of Virology. And theoretically, a sample collected in a foreign government belongs to the foreign government so yeah.

Q. But the WIV has been debarred. They can't participate in this grant?

A. Yeah. And they are not participating in this grant.

Q. But they have custody of all the samples?

A. But we have got information, data from the samples that has not yet been analyzed. We have that information here in the U.S.

Q. But the Latinne paper, you said that was all your information?

A. Since the Latinne paper, since the pandemic began, Wuhan Institute of Virology's staff has continued to sequence out some of those initial small fragments to get whole genome sequences, critical information. I agree with what Dr. Erbelding and Stemmy or whoever it was has said that that was paid for by U.S. taxpayers. It is our right to get that information. We've got it and we're now working on it to publish that information.

Q. Is there information derived from the samples that you don't have?

A. From what I hear, no. Not -- until they do more work on them. And then we have an understanding that we'll be able to get some access to those data too.

Q. I'm trying to understand how this works. With the WIV debarred, and not talking to you anymore, which –

A. Well, they do talk to us. I can talk to them. It's not illegal to talk to them.

Q. No, no, no. But you said, like, we've asked them for the progress reports, they never answered an email.

A. I asked them for the lab notes.

Q. For the lab notes.

A. Yeah, yeah.

Q. But your -- I'm trying to understand how we have debarred them, but we're still paying them to process samples.

A. No, no. There's no money going to Wuhan Institute of Virology at all. No money going to China.

Q. So there's a bolus of data that left the WIV before they were suspend -- between -- before they were suspended that has yet to be analyzed, that has to be analyzed or that need - -

A. My understanding is that the debarment is they are not able to take Federal funds, now for 10 years. I think at least that is, what I understand, from what the phrase means. They have other samples. If they are going to do further work on those samples and they are willing to give us that information, that's a positive win for the U.S. taxpayer.

Q. Sure.

A. I'm going to take the opportunity and publish it, and I think that's a good thing.

Q. So why do you think the difference? Why do you think the difference in the WIV is willing to give you access to the samples, the results of tests on these samples but not the laboratory notebooks?

A. Well, you would have to ask WIV about that. I'm very delighted that we've been able to get that. Information out of WIV and out of China. It's a good thing.

Q. And they are, functionally, doing it for free? We may have some prior claim on it because the initial sampling was done with our money.

A. Yeah, unfortunately, the legalities of ownership are not good and not clear in this sort of issue. However, if we can get the data, we're going to get it and we're going to work it and we are going to make

it public and we are going to try and get at much good information as we can out of it.[308]

According to Dr. Erbelding, Dr. Daszak failed to inform NIH that a substantial number of samples or sequences—the same samples or sequences that were a primary purpose for reinstating EcoHealth's previously suspended grant—were in the custody and control of the WIV, a now debarred organization. It remains unclear how many samples or sequences that the federal government paid for still reside at the WIV.

Since access to sequences and samples was a substantial reason for reinstating EcoHealth's grant, it raises the question of whether NIH would have still reinstated the grant if it had knowledge of this issue. According to Dr. Erbelding, if she had that knowledge, it would have at least caused her to ask more questions regarding the reinstatement.

Dr. Emily Erbelding

Q. I have one quick follow-up question, and then I'm going to ask some more about EcoHealth and their various efforts. If Dr. Daszak had told you that samples were still in the custody and control of the Wuhan Institute of Virology, would that have changed your calculus in reinstating the grant?

A. I think it depends on -- we would have said those samples, we can't assume that they're going to be used. It would have depended upon what other samples he did have access to or he did have in other locations that were accessible.

Q. So it would have at least prompted some follow-up questions or more information?

A. Yes.

Q. All right. Thank you.

A. I think so.[309]

Dr. Daszak later testified that Dr. Erbelding mistook samples for sequences and that he clearly stated EcoHealth had access to sequences and then samples from elsewhere in S.E. Asia.

Dr. Peter Daszak (May 1, 2024)

[308] Daszak TI, *supra* note 253, at 263-265.
[309] Erbelding TI, *supra* note 281, at 90.

Q. You testified a couple of minutes ago that you were very forthright with NIH and NIAID that you actually didn't have access to the samples.

A. Correct.

Q. Is Dr. Erbelding lying?

A. …Clearly, Dr. Erbelding either wasn't in the conversation where I clearly stipulated we do not have access to those samples; we do have access to the sequences, or perhaps she has mistaken sequences for samples…what matters is the record, which is the emails sent to NIH proposing the work to be done and the revised specific [aims], which clearly state no further samples will be brought out of China and that sequences are already in EcoHealth's possession.[310]

Dr. Tabak was asked about Dr. Erbelding' s testimony.

Dr. Lawrence Tabak (May 16, 2024)

Q. …Dr. Tabak, do you think it is likely that the director of NIAID's Division of Microbiology and Infectious Diseases does not understand the difference between sequences and samples?

A. I am sure she does.[311]

Dr. Daszak omitted the material fact that the sequences and samples the federal government were paying for were, at least in part, under the custody and control of the WIV. Further, testimony suggests that if NIH had known this, it would have resulted in more questions regarding whether to reinstate the grant or not.

FINDING: The Defense Advanced Research Projects Agency Rejected EcoHealth Alliance, Inc.'s DEFUSE Proposal Because of a Lack of Gain-of-Function or Dual Use Research of Concern Plan.

In 2018, DARPA began accepting applications for federal funded research pursuant to a new program entitled PREventing Emerging Pathogenic Threats [hereinafter "PREEMPT"]. This program was designed to "target viral biothreats within animal reservoir to preempt their entry into human populations before an outbreak occurs."[312] Dr. Gimlett was the Program Officer at DARPA in charge of the PREEMPT program. Dr. Gimlett described his responsibilities as:

Dr. James Gimlett (May 9, 2024)

[310] Daszak Hearing, *supra* note 259, at 52.
[311] Tabak Hearing, *supra* note 246, at 23.
[312] *PREEMPT Proposers Day*, DARPA, *available at* https://events.sa-meetings.com/ehome/299628/648416/.

Q. Those were your responsibilities generally. What were your responsibilities specific to PREEMPT?

A. So basically formulate the concept, which was my concept; canvas the community to sort of understand where the state of the art was, potential performers, trying to get the word out that we were interested in this, solicit feedback; and eventually create a definition for what the program looks like, get buy-in from the level of management at DARPA, which meant office directorship and then DARPA directorship. And basically that means going through a few hurdles, like acceptance from your colleagues, who are also aiming to shoot you down if you don't have it thought through. So it's basically kind of get the details right on how the program gets then communicate it to the community in a broad area announcement. Subsequent to that, go through the source selection process, which means reviewing the proposals. My job as a reviewer would be on the technical side of the proposal review, and then there's additional review after that that would come from the office leadership or from legal or other -- contracts office, for example -- and then manage the program.[313]

PREEMPT would be divided into two technical areas. According to Dr. Gimlett, Technical Area 1 was:

Dr. James Gimlett (May 9, 2024)

Q. And what were kind of the goals or strategy of the PREEMPT program?

A. So it started from sort of a hypothesis that we've had a lot of close calls in zoonotic spillover and had gotten fairly lucky that most of them were semi-contained. But I wasn't happy with the overall approach, which is, okay, let's hope we don't -- let's hope we get lucky again, wait until another spillover happens and then try to rush and contain it through all kinds of draconian measures sometimes. So the idea was can we do a better job of sort of sampling the hotspot areas of the globe where this is happening frequently, especially both in the wild animal reservoir, as well as in livestock reservoirs and humans associating with those two; get a better gauge of sort of a probabilistic likelihood and try to come up with some models for how easy -- how likely a spillover could happen; try to get a little bit in front of the curve and even possibly think about ways of sort of

[313] Transcribed Interview of James Gimlett, M.D., Dir., Program Office, Defense Advanced Research Projects Agency, at 9 (May 9, 2024) [hereinafter "Gimlett TI"].

stopping it in its tracks before it hits the human population. So that was the overall goal.[314]

Dr. Gimlett described Technical Area 2:

Dr. James Gimlett (May 9, 2024)

Q. No, no, no. I appreciate it. Would it be more of a surveillance program? You said, like, kind of the end goal is stopping it before the human -- before human spillover. And we'll get into DEFUSE with, like, kind of the aerosolized bat vaccine that they proposed. But was it more heavily focused on surveillance or more heavily focused on kind of stopping the spillover?

A. It was more -- in my mind, it was more heavily focused on the surveillance and analytics at the front end and trying to do a better job of assessing likelihood of spillover. So the program was divided into two technical areas. That was technical area one. Technical area two was sort of -- it was basically pinging the community to see if there were any ideas on how to preempt, literally, a spillover either at the vector if it was mosquito borne, at the sort of livestock if it was passing through livestock before entering the human population, or directly in the wild animal reservoirs. And it was more assess what's possible, sort of the art of the possible, and if you had some solution to validate it in some kind of closed, confined, safely controlled area. So that was the idea. It wasn't actually go out and do it. It was to see what is possible to be done in a controlled experimental environment.[315]

***

Q. And the goal kind of on part two, like you said, would have been to do it in a controlled research environment, not necessarily go to the source and release?

A. Correct. That would have been beyond that program's scope.[316]

After DARPA received proposals, DARPA conducted a three-person peer review.[317] These reviewers judged each proposal on (1) the "technical approach, competence, plausibility, innovation, whether [DARPA] thought it was outlined in a way that you could kind of get to the ultimate goal of the program in a reasonable timeframe"; (2) "[t]he sort of relevance to the

[314] Gimlett TI, *supra* note 313, at 10.
[315] Gimlett TI, *supra* note 313, at 11.
[316] *Id.*
[317] Gimlett TI, *supra* note 313, at 13.

DOD"; and (3) "cost realism, so was it actually budgeted to do the job."[318]After the peer review concluded, each proposal was graded as (1) selectable, (2) selectable, but not recommended for funding, or (3) not selectable.[319]

In the end, it was Dr. Gimlett who would make the recommendation to DARPA leadership and then the DARPA Director or Deputy Director would make the final funding decision.[320]

On March 24, 2018, a consortium of researchers led by Dr. Daszak and EcoHealth submitted a proposal to DARPA named "Project DEFUSE: Defusing the threat of Bat-borne Coronaviruses" [hereinafter "DEFUSE"].[321] In Technical Area 1, the stated goal of DEFUSE was:

> In TA1 we will intensively sample bats at our field sites where we have identified high spillover risk SARSr-CoVs. We will sequence their spike proteins, reverse engineer them to conduct binding assays, and insert them into bat SARSr-CoV (WIV1, SHC014) backbones (these use bat-SARSr-CoV backbones, not SARS-CoV, and are exempt from dual-use and gain of function concerns) to infect humanized mice and assess capacity to cause SARS-like disease.[322]

In Technical Area 2, the stated goal of DEFUSE was:

> In TA2, we will evaluate two approaches to reduce SARSr-CoV shedding in bat caves: (1) Broadscale immune boosting, in which we will inoculate bats with immune modulators to upregulate their innate immune response and downregulate viral replication; (2) Targeted immune boosting, in which we will inoculate bats with novel chimeric polyvalent recombinant spike proteins plus the immune modulator to enhance innate immunity against specific, high-risk viruses…**The most effective biologicals will be trialed in our test cave sites in Yunnan Province**, with reduction in viral shedding as proof-of-concept.[323]

On its face, this type of research is dangerous and, specifically regarding Technical Area 2, EcoHealth's proposed experiments—conducting trials in uncontrolled cave environments—violated the scope of PREEMPT. Furthermore, some scientists have even pointed to DEFUSE as a type of research that can create a virus like COVID-19.[324]

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[318] Gimlett TI, *supra* note 313, at 15.
[319] Gimlett TI, *supra* note 313, at 16.
[320] *See generally*, Gimlett TI.
[321] EcoHealth Alliance, Inc., *Proposal* - Project DEFUSE: Defusing the threat of Bat-borne Coronaviruses, HR001118S0017-PREEMPT-PA-001 (Mar. 27, 2018).
[322] *Id.*
[323] *Id.*
[324] Chan, *supra* note 18.

Prior to submission of EcoHealth's full proposal, EcoHealth had the opportunity to attend a "Proposers Day" and, subsequent to that, submit an abstract for preliminary review by DARPA. According to Dr. Gimlett, Dr. Daszak was present for "Proposers Day" and submitted an abstract for preliminary review.[325] After DARPA and Dr. Gimlett reviewed EcoHealth's abstract, Dr. Gimlett and Dr. Daszak discussed it.

Dr. James Gimlett (May 9, 2024)

Q. And then the conversation that you had with Dr. Daszak afterwards, were there tweaks you wanted him to make? How was that, the encouragement of a proposal, communicated?

A. So it's generally: Here's some really strong pieces that we think have merit. In their case, it was they have their feet on the ground in a very hotspot for zoonotic spillover, with access to bats and bat caves and even a whole repertoire of prior samples that they've collected and only partially analyzed. So that was attractive. I don't recall the exact feedback he would have given me on that, other than be sure to read the BAA. We're particularly interested in quantitative models, so connect your sampling with some kind of approach to get a risk map and a likelihood model of spillover. There's a bunch of safety concerns as well, and please read the BAA about things that might be of ELSI, which is ethical, legal, societal impact, as well as safety concerns. So that would have been the feedback to everybody.[326]

It was also at this stage that Dr. Daszak asked DARPA about the inclusion of a Chinese partner, specifically the WIV.[327] According to Dr. Gimlett, DARPA approved the use of a Chinese collaborator.

Dr. James Gimlett (May 9, 2024)

Q. And it sounds like they had -- at this point had they informed DARPA that they were planning on using the Wuhan Institute?

A. Yes. So he would have talked about that and probably would have asked us: Is it okay to have a Chinese partner? And I wouldn't have been able to give him the answer. So this PREEMPT is a 6.1 research proposal. There's no official restriction on who can perform. And often DARPA does rely on researchers outside of the country. They're often teamed with U.S. researchers as well. But DARPA goes where the expertise is, or in this case where the samples exist. So there wouldn't have been any official restriction. I basically asked

[325] Gimlett TI, *supra* note 313, at 20.
[326] *Id.*
[327] Gimlett TI, *supra* note 313, at 21.

up the chain: Is it okay? Because I don't have any awareness of China being a performer on a DARPA program, certainly didn't have any on mine. So it would have been a little bit unusual, but probably not strictly prohibited. So I went up the chain, and the answer came back: No, we're not going to restrict. Yeah. So that was communicated back, that, yes, it's okay to have a Chinese partner.

Q. We've heard from NIH and EcoHealth on a different grant that foreign labs, foreign collaborators are vetted through the State Department. How does DARPA vet foreign labs or collaborators?

A. That I don't know.

Q. Would there be vetting beyond just the review process? If you know.

A. There would probably be vetting at the contractual process, which generally does not involve the program manager, more on the technical side, but probably there'd be vetting at that level.

Q. Again, to the extent you know, when particularly work with China, beyond going up the chain in DARPA, do you know if there was any question to the intelligence community at large on the use of a Chinese lab?

A. No, I don't know. I mean, there certainly would have been concerns about whether the information flow would allow access to the data, and that would have been part of that vetting process as well, I'm guessing, because China had just come out with some new policies on data export controls. So that would have been something to be discussed, but not at my level.[328]

In addition to EcoHealth's summaries of Technical Areas 1 and 2, EcoHealth—via DEFUSE—also proposed:

After receptor binding, a variety of cell surface or endosomal proteases cleave the SARS-CoV S glycoprotein causing massive changes in S structure and activating fusion-mediated entry. We will analyze all SARSr-CoV gene sequences for appropriately conserved proteolytic cleavage sites in S2 and for the presence of potential furin cleavage sites. SARSr-CoV S with mismatches in proteolytic cleavage sites can be activated by exogenous trypsin or cathepsin L. Where clear mismatches occur, we will introduce appropriate human-specific cleavage sites and evaluate growth potential in Vero cells and HAE cultures.[329]

[328] Gimlett TI, *supra* note 313 at 21-22.
[329] EcoHealth Alliance, Inc., Proposal - Project DEFUSE: Defusing the threat of Bat-borne Coronaviruses, HR001118S0017-PREEMPT-PA-001 (Mar. 27, 2018).

Scientists believe COVID-19's furin cleavage site located at the S1/S2 juncture of the spike protein of the virus to be a primary driver in infectability in humans.[330] Furthermore, no sarbecoviruses—the subgenus of coronaviruses COVID-19 belongs to—are known to have a furin cleavage site. EcoHealth's proposed research could have resulted in a unique virus such as COVID-19.

However, Dr. Daszak did not discuss this specific research during the abstract phase of the DEFUSE proposal.[331] Dr. Gimlett was surprised by this lack of discussion and this specific research's inclusion in EcoHealth's final DEFUSE proposal.[332]

Dr. James Gimlett (May 9, 2024)

Q. So that opens up new questions. So the kind of -- and I'm going to butcher the science a little bit -- but the proposal of taking 20 percentage divergent SARS-related coronaviruses, dropping in a furin 1 cleavage site at S1/S2, and testing pathogenicity was not in the original Proposers Day or abstract?

A. **It wasn't at the abstract or Proposers Day** that I would remember, no. That's why I kind of hedged a little bit, surprising.

Q. That part of the proposal was surprising?

A. Yes.[333]

In addition to being surprised at this new proposal, Dr. Gimlett also expressed concerns regarding the safety of EcoHealth conducting this kind of research.

Dr. James Gimlett (May 9, 2024)

Q. Why? I mean, beyond that he hadn't mentioned it before, did it pose particular risks?

A. Well, so to answer that, we kind of have to back up, if it's okay with you, just to --

Q. Yes.

A. So before the BAA even went out, we did a lot of research on all the government regulations involving gain-of-function research, dual-use research of concern. There was some language about basically

[330] Chan, *supra* note 18.
[331] EcoHealth Alliance, Inc., Proposal - Project DEFUSE: Defusing the threat of Bat-borne Coronaviruses, HR001118S0017-PREEMPT-PA-001 (Mar. 27, 2018).
[332] Gimlett TI, *supra* note 313, at 23-24.
[333] Gimlett TI, *supra* note 313, at 23-24.

this P3CO, so potential pandemic pathogen documentation that had come out. All of which were very -- they all had their own viruses of interest. Like gain-of-function, the original moratorium was specifically about avian influenza and SARS and MERS. The P3CO had a broader set of pathogens, not all viral, and it specifically talked about gain of transmissibility or virulence, but it said it was not -- that did not apply to wild type viruses not in humans. So when we put together the BAA, I was concerned that regardless of what the official language is, since this is going out to the academic community and others who will basically not -- they will not want to be constrained in terms of how they publish information, being in a 6.1 research, and DARPA had no formal mechanism to restrict that. But I'm still concerned that if this ever gets into the area where there could be dual-use research of concern, you've somehow created something that you didn't intend and it's more virulent and transmissive. And I don't want to see that sequence published the next day in some journal. So we insisted on sort of a safety and communication plan in the BAA: Tell us what is your mechanisms to put a halt or a slowdown on anything in case you encounter this situation. So this is sort of preamble to why this sort of struck us in an odd way, because the intent of PREEMPT really was to look at natural spillover processes. So we weren't even expecting that it would encounter dual-use issues but wanted that protection mechanism anyway just in case. And I did not want to see sort of, well, a narrow interpretation, since it's not these specific viruses, it doesn't apply. And reading the proposal is the first time that they did talk about engineering chimeric viruses, albeit still just taking components of wild virus found in bat caves, but mixing and matching to potentially gain -- probably to gain ability to even culture in, like, human cell cultures. So I understood the rationale, but it didn't quite map to what I was looking for, and I wasn't sure how that would help necessarily in producing probabilistic risk map, and they didn't go through clearly that motivation and how they were going to use that data. So all of these were concerns, particularly the claim that since this is a wild bat virus, gain-of-function, dual use, none of it is relevant, and we don't have to go any further. That was not what the BAA specified. So now I don't remember the original question, whether I got to it in some way, 1 but this is a complicated story. I just want to get it clear.

Q. No. Absolutely. I think you did a little bit. I think the original question in this case was does that proposed work strike particular risks that were not envisioned.

A. So, I mean, any time you put a virus in some other animal, in a petri dish, in a cell culture, there are some risks. And any time anyone

gets infected by a virus, the virus will be looking to gain function in some respect. So there's always risks. And I wanted to be sure that this program had clear safety guidelines, where it would be done, in the BSL-3, if it was a coronavirus with pandemic potential. And even if it's a bat virus, it could still have risks. I mean, there are always -- it is spilling over, and there's probably some component in that viral quasi species that's capable of entering other mammalian cell types. So this does encounter -- and it's hitting a gray area that was a concern, and we just wanted to make sure that we never got -- crossed that line.[334]

After review, DARPA marked the DEFUSE proposal as "selectable, but not recommended."[335] A letter was leaked that purported to be the denial letter from Dr. Gimlett to Dr. Daszak.[336] Dr. Gimlett confirmed the accuracy of this letter.

Dr. James Gimlett (May 9, 2024)

Q. Okay. I'll introduce majority exhibit 3 and have some preliminary questions about this before getting into the specifics. At least on its face, it appears to be the denial letter to EcoHealth under PREEMPT. It has your signature block that is not signed. So, just an initial question of, is this a letter that you would have typed out?

A. Yep. That -- that looks like the letter I wrote.

Q. Was it formally sent to EcoHealth, or was it more communicated verbally?

A. No, it would have been formally sent.[337]

DEFUSE was not selected for funding by DARPA for numerous reasons. According to DARPA's rejection letter, DARPA was concerned that EcoHealth's research proposed in DEFUSE would meet the definition of gain-of-function research or dual use research of concern [hereinafter "DURC"].[338]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[334] Gimlett TI, *supra* note 313, at 24-26.
[335] Letter from James Gimlett, M.D., Program Manager, DARPA, to Peter Daszak, Ph.D., Pres., EcoHealth Alliance, Inc. (On File with Select Subcomm. Staff).
[336] *Id.*
[337] Gimlett TI, *supra* note 313, at 41-42.
[338] Gimlett Letter, *supra* note 335.

The team discusses risk mitigation strategies to address potential risks of the research to public health and animal safety but does not mention or assess potential risks of Gain of Function (GoF) research and DURC. Given the team's approach does potentially involve GoF/DURC research (they aim to synthesize spike glycoproteins that may bind to human cell receptors and insert them into SARSr-CoV backbones to assess capacity to cause SARS-like disease), if selected for funding an appropriate DURC risk mitigation plan should be incorporated into contracting language that includes a responsible communications plan.

James Gimlett, Ph.D.
Program Manager
Biological Technologies Office

In a transcribed interview, Dr. Daszak refuted this, and testified that DEFUSE was not funded because DARPA did not have sufficient funds.

Dr. Peter Daszak (November 14, 2024)

Q. And as you said, DARPA denied it. Did you ever submit this proposal to any other funding agencies?

A. Well, there was a little bit said about DARPA declining to fund this, including people who have said that they declined it because of biosecurity concerns. Absolutely not true. We had an interview with DARPA specifically so they could inform us why it was rejected. I have got the contemporaneous notes right here, never once did biosafety come up. It was too much money. They didn't have enough money. It was too 1 ambitious, which is standard grant -- agency language for too ambitious. So just a little miff around that. I forgot the question, though.[339]

However, Dr. Gimlett testified that biosecurity concerns were one of the three reasons that EcoHealth's DEFUSE proposal was denied.

Dr. James Gimlett (May 9, 2024)

Q. Dr. Daszak testified that the reason that this was not funded was strictly because there was not enough money. This seems to go further than just it's an expensive proposal. I guess -- and the letter is in your own words, but sitting here today, what do you recall as the primary drivers to deny funding?

[339] Daszak TI, *supra* note 253, at 260-261 (As of publication of this Report, although Dr. Daszak testified he had contemporaneous notes between himself and DARPA, Dr. Daszak never produced those notes to the Select Subcommittee despite being requested.).

A. I would say three major things, which we've kind of talked about all of them. One, no regulatory or ELSI discussion. Two, no, sort of, justification for collect -- of basically, acquiring a whole set of data based on, sort of, genetic manipulation of the virus, how that data would then inform a model, for example. So the model development which we've talked about in the letter. And then, three, didn't address -- or basically just denied that they had to address gain-of-function because it didn't fall under any of the regulatory requirements. So those three were key reasons in my mind.[340]

***

Q. Yeah. So was kind of the lack of safety proposal both in communications of the results and in the actual research a reason for denial?

A. It was. I mean, so safety kind of hits on two different levels. One is safety in terms of how the samples are acquired or how and where the research is done, and that seemed to be addressed in the proposal. But it also requires what happens if, during these kinds of assaying and manipulation tests, you all of a sudden stumble on something that's highly infectious, how are we going to, sort of, reanalyze whether we proceed with this research or not. And that was the safety piece that was missing.

Q. So the actual, like, "Oh, no, we found something that was more transmissible or more lethal, what do we do next," was the safety -- was the biosafety –

A. Yeah. So, in my mind, regardless of whether that falls strictly under gain-of-function, the virus has potentially gained some function that could be hazardous, and we needed -- we need to reassess whether to proceed with research or put it in a 1 different safety level or something.[341]

Dr. Gimlett directly contradicted Dr. Daszak's testimony regarding the rejection of DEFUSE. Dr. Gimlett testified unequivocally that EcoHealth's lack of a gain-of-function or DURC plan was part of the rationale to reject the DEFUSE proposal.

Dr. James Gimlett (May 9, 2024)

[340] Gimlett TI, *supra* note 313, at 43-44.
[341] Gimlett TI, *supra* note 313, at 44-45.

Q.	And we've kind of touched on this, but I'm going to ask it a little bit more bluntly. Did the lack of a gain-of-function or DURC plan affect the decision to reject the proposal?
A.	Yes, it did.[342]

EcoHealth and Dr. Daszak proposed research in DEFUSE that was inherently dangerous and could have created and released a virus like COVID-19. Dr. Daszak initially hid the most dangerous aspect of this research from DARPA. Dr. Daszak declined to provide a required gain-of-function or DURC plan, even though his research may have resulted in a virus gaining function. Finally, DARPA denied to fund DEFUSE in part because of this lack of gain-of-function or DURC plan—contrary to Dr. Daszak's testimony.

FINDING:	The Department of Justice Empaneled a Criminal Grandy Jury to Investigate the Origins of COVID-19.

EcoHealth was subject to numerous federal investigations regarding both its potential role in the COVID-19 pandemic, but also multiple accusations surrounding violated federal grant policies. The outcomes of most of these investigations are public.

However, the Select Subcommittee discovered that DOJ was also investigating the origins of COVID-19. The specific details of the investigation are unknown but, based on documents, it appears the DOJ's investigation involves EcoHealth's role in the COVID-19 pandemic.[343] As of December 4, 2024, the outcome(s) of DOJ's investigation are not public.

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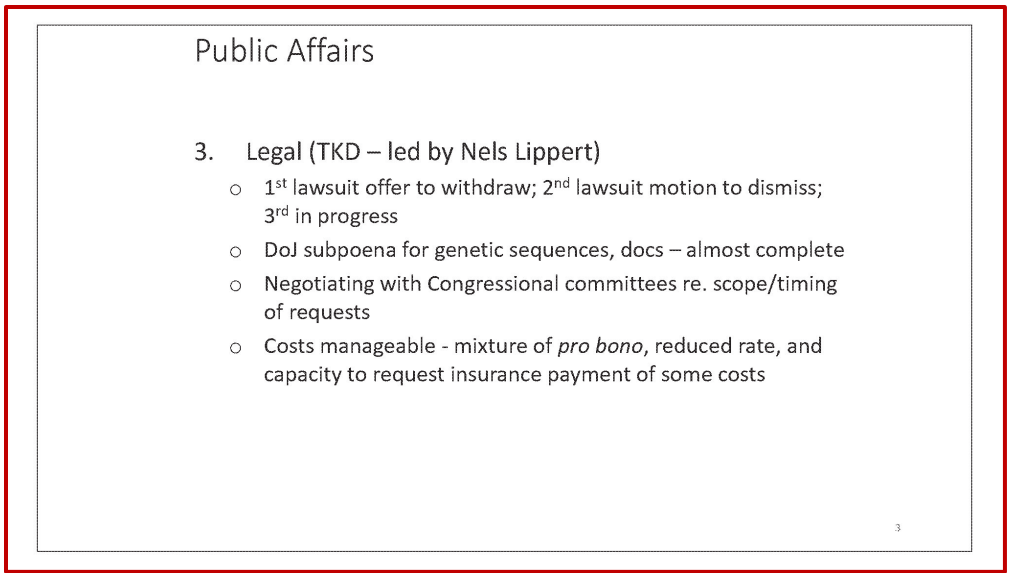
[342] Gimlett TI, *supra* note 313, at 46.
[343] E-Mail from Counsel for EcoHealth Alliance, Inc., to Peter Daszak, Ph.D., EcoHealth Alliance, Inc. (Feb. 6, 2023, 12:01 PM). (The Select Subcommittee obtained communications between EcoHealth and its counsel that EcoHealth was with withholding pursuant to attorney-client privilege because Dr. Daszak and his counsel included non-clients on the e-mails, thus piercing the privilege.)


Public Affairs
3. Legal (TKD – led by Nels Lippert)
1st lawsuit offer to withdraw; 2nd lawsuit motion to dismiss; 3rd in progress
DoJ subpoena for genetic sequences, docs – almost complete
Negotiating with Congressional committees re. scope/timing of requests
Costs manageable - mixture of pro bono, reduced rate, and capacity to request insurance payment of some costs
3

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Message

From: [redacted]
Sent: 2/13/2023 10:56:59 PM
To: Peter Daszak [redacted]
CC: Aleksei Chmura [redacted] Jeff Sturchio [redacted]
Subject: FW: Draft Letter to Energy & Commerce Staff [IMAN-DOCUMENTS.FID794944]

Hi Peter. In response to your Oversight/Coronavirus Subcommittee draft letter, received just now, I'm forwarding as my only comment the highlighted thoughts below from the Energy draft from last week. (It pertains to the second paragraph of the current draft letter.) Other than that, I would just cc me in the text or the transmittal e-mail. Let us know if you have q's or want to talk. Thanks again, MG

Tarter Krinsky & Drogin

[redacted]
Tarter Krinsky & Drogin LLP
1350 Broadway|New York|NY|10018
www.tarterkrinsky.com|LinkedIn

Crain's 2022 best places to work in NYC

From: [redacted]
Sent: Monday, February 6, 2023 12:01 PM
To: Peter Daszak [redacted] Aleksei Chmura [redacted] Jeff Sturchio [redacted]
Subject: Draft Letter to Energy & Commerce Staff [IMAN-DOCUMENTS.FID794944]

Hi Peter. I've reviewed the draft and discussed it briefly with Nels. Looks good subject to the one typo and suggestion in the attached markup.

The only thought is whether to skip for the time being reference to our other government inquiries. I suppose we can always recite those if we get any pushback on a reasonable extension, but I don't expect that, given the non-compulsory nature of the current request. Especially on the Executive Branch front, where the DOJ grand jury investigation seems so far to remain nonpublic, I think it would be better just to say we're acting as promptly as possible under the circumstances without inviting inquiry into other demands for info.

Just a thought, but subject to that it's good to go from our perspective. Thanks.

p.s. Just a reminder, there's a communication from Ravi Batra we wanted to discuss with you. Don't really need me for that, but I know Nels and Matt would like to catch up when you can.

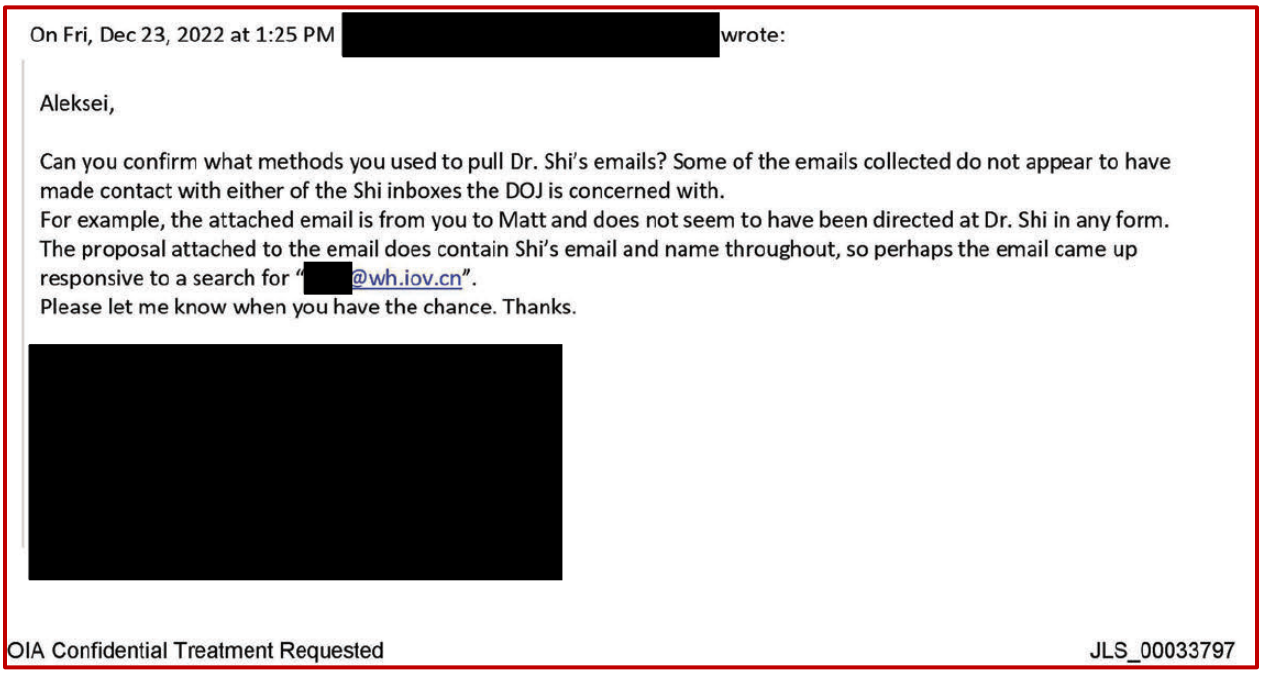
On November 1, 2024, the Select Subcommittee requested EcoHealth confirm the existence of a DOJ Grand Jury investigation.[344] EcoHealth's counsel responded:

> Regarding your inquiry about the DOJ, we decline generally to provide any information about the existence or nonexistence of any investigation other than the SSCP's own. For the avoidance of doubt this response should not be read to confirm or deny the existence of any investigation.[345]

[344] E-Mail from Select Subcommittee Staff to Counsel for EcoHealth Alliance, Inc. (Nov. 1, 2024, 9:54 AM).
[345] E-Mail from Counsel to EcoHealth Alliance, Inc. to Select Subcommittee Staff (Nov. 1, 2024, 6:25 PM).

On November 15, 2024, the Select Subcommittee again requested information regarding the existence of a DOJ Grand Jury investigation. During this call, EcoHealth's counsel assured the Select Subcommittee the investigation was not into EcoHealth nor Dr. Daszak.

According to documents, DOJ subpoenaed EcoHealth's communications with, at least, Dr. Shi. This subpoena included both Dr. Shi's official WIV e-mail address and her personal hotmail address.[346]



On Fri, Dec 23, 2022 at 1:25 PM [redacted] wrote:

Aleksei,

Can you confirm what methods you used to pull Dr. Shi's emails? Some of the emails collected do not appear to have made contact with either of the Shi inboxes the DOJ is concerned with.
For example, the attached email is from you to Matt and does not seem to have been directed at Dr. Shi in any form. The proposal attached to the email does contain Shi's email and name throughout, so perhaps the email came up responsive to a search for "[redacted]@wh.iov.cn".
Please let me know when you have the chance. Thanks.

[redacted]

OIA Confidential Treatment Requested JLS_00033797

[346] E-Mail from Counsel to EcoHealth Alliance, Inc. to Aleksei Chmura, Ph.D., Chief of Staff, EcoHealth Alliance, Inc. (Dec. 23, 2022, 1:25 PM).

III. The Failures of the National Institutes of Health and National Institute of Allergy and Infectious Diseases

FINDING:	The U.S. National Institutes of Health and National Institute of Allergy and Infectious Diseases Failed to Oversee EcoHealth Alliance, Inc. .

In response to allegations regarding EcoHealth's actions—including concerns that the research conducted at the WIV funded by NIAID and may have started the COVID-19 pandemic—the NIH began compliance actions regarding the grant. These actions centered around EcoHealth's administrative and scientific failures.

There is very little accountability regarding the approval of grants. Technically, the Director of NIAID approves grants for funding. In reality, the peer review process limits exposure and restricts Congress' ability to oversee federal funding. Dr. Fauci testified, that as Director of NIAID, he simply signs off on grants without reviewing them.

Dr. Anthony Fauci (January 8, 2024)

Q. Who gives the final approval?

A. You know, technically, I sign off on each council, but I don't see the grants and what they are. I never look at what grants are there. It's just somebody at the end of the council where they're all finished and they go, "Here," and you sign it.[347]

The Trump Administration Identified EcoHealth's Actions and Instructed NIH To Remedy It

On April 17, 2020, during a press conference, President Trump identified EcoHealth's grant, and any other grants going to China, as potentially problematic.

Coronavirus Task Force Briefing (Apr. 17, 2020)

Q. Thank you, Mr. President. U.S. intelligence is saying this week that the coronavirus likely came from a level 4 lab in Wuhan. There's also another report that the NIH, under the Obama administration, in 2015 gave that lab $3.7 million in a grant. Why would the U.S. give a grant like that to China?

THE PRESIDENT: The Obama administration gave them a grant of $3.7 million? I've been hearing about that. And we've instructed that if any grants are going to that area — we're looking at it, literally, about an hour ago, and

[347] Fauci TI 1, *supra* note 225, at 83.

also early in the morning. We will end that grant very quickly.[348]

On April 18, 2020, Dr. Tabak directed Dr. Lauer to send a letter to EcoHealth and instruct them to terminate all funding to the WIV.[349] On April 19, 2020, Dr. Lauer sent this letter.[350] On April 24, 2020, Dr. Tabak directed Dr. Lauer to send a letter to EcoHealth terminating its entire grant.[351] Dr. Lauer was not involved in the discussions or drafting of ether letter and did not have knowledge of how the decision originated. Importantly, however, Dr. Lauer agreed with the letters' contents and justifications.

Dr. Michael Lauer (Nov. 2, 2023)

Q. Did you review the letter before it was sent?

A. Yes.

Q. And did you agree with its contents and the justifications provided in it?

A. Yes.[352]

Through the Select Subcommittee's investigation, evidence discovered suggests that the decision to terminate the EcoHealth grant originated from Mr. Mark Meadows, Chief of Staff to President Trump.

Dr. Lawrence Tabak (Jan. 5, 2024)

Q. So like I said, this is Majority Exhibit 7. It's an April 19th, 2020 letter from Dr. Lauer to EcoHealth and Columbia -- I believe Columbia was on there by mistake -- but primarily to EcoHealth, notifying EcoHealth that they're not to provide funds to the Wuhan Institute of Virology anymore pursuant to a couple regulations and OMB provisions. Were you aware of this letter at the time it was sent?

A. I was.

Q. Did you have any discussions with anyone about this letter prior to it being sent?

[348] Remarks by President Trump April 17, 2020, *supra* note 220.
[349] Lauer TI, *supra* note 262, at 40.
[350] Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Peter Daszak, Ph.D., *et. al.,* Pres., EcoHealth Alliance, Inc. (Apr. 19, 2020).
[351] Lauer TI, *supra* note 260, at 48.
[352] Lauer TI, *supra* note 260, at 49.

A. Yes.

Q. Who?

A. I discussed this letter with Dr. Lauer and I discussed this letter with Dr. Collins. I don't know if I discussed it with anyone else.

Q. Do you remember how this -- the drafting process of this letter, how it came to be?

***

A. Okay. So this was done with the help of a senior administrative official. That's really all I could say.

Q. Can you give me a little bit more generality about that? A grants officer? A program officer? Who was the –

A. A senior administrative official.

Q. Who is that?

A. That's –

Q. The who isn't deliberative.

***

A. Mr. Charrow.

Q. The Office of General Counsel at HHS?

A. Correct.

Q. All right. Is this the first time or the days preceding this that you became aware of efforts to suspend or terminate or otherwise alter the EcoHealth grant?

A. I don't remember the dates. I remember the -- but I remember the event that was time-sensitive. Former President Trump was to give a news conference of some sort, and apparently he wanted to articulate that this had been suspended, and so that was the time sensitivity.

Q. And who communicated that sensitivity to you?

***

A. Mr. Charrow.

Q. Okay. And do you know who had communicated with Mr. Charrow?

***

A. I was told who it was, but I don't have any evidence of who it was.

Q. Who were you told who it was?

***

A. Okay. My secondhand knowledge is that it was the White House chief of staff.

Q. Mark Meadows?

A. Correct.

Q. Thank you. I want to then -- well, I'm going to summarize the timeline then leading up to April 19th without getting into any of the discussions of how April 19th happened. Your understanding -- and, granted, some of this is secondhand -- is a conversation took place between Chief of Staff Meadows and Mr. Charrow, who then had a conversation with you, and then you had a conversation with Dr. Lauer that resulted in this letter?

***

A. That is correct.[353]

This sequence of events was confirmed by Dr. Fauci.

Dr. Anthony Fauci (Jan. 8, 2024)

Q. This is a letter sent from Dr. Lauer to Drs. Chmura and Daszak from April 24th, 2020 -- so 5 days after this one was sent -- that terminates the entire grant "Understanding the Risk of Bat Coronavirus Emergence." Were you previously aware of this letter?

A. Let me read it. Hold on. I was aware that the grant was terminated. I'm not -- I don't recall this particular letter that I saw at the time. I

[353] Tabak TI, *supra* note 83, at 53-58.

think I was shown -- I don't think I was shown this, but I don't recall seeing this letter at the time it was sent.

Q. You testified in June of 2020 before the House Committee on Energy and Commerce. You were asked about this grant and the cancellation and said, "Why was it canceled? It was canceled because the NIH was told to cancel it. I don't know the reason, but we were told to cancel it." Do you have any recollection of who told you to cancel it?

***

Q. All right. I'll relay to you what Dr. Tabak told us was the chain of events, and you can just tell me if that's accurate to the best of your recollection. Dr. Tabak testified that Chief of Staff Mark Meadows called the Office of General Counsel at HHS, who then called Dr. Tabak, who then called Dr. Lauer, who was instructed to cancel the grant. Is that consistent with your memory?

A. Yes.[354]

By April 17, 2020, the White House was reviewing both the EcoHealth grant and other grants that involved China to ensure they were in compliance with all applicable grant terms and conditions. After this review, Mr. Meadows identified EcoHealth and its subgrant to the WIV as being problematic and instructed HHS to first terminate the subaward and then the entirety of the grant. Dr. Lauer, the NIH official in charge of grant compliance, testified that he was unaware of EcoHealth or that it was out of compliance prior to April 19, 2020.[355] If not for the actions of the Trump Administration, this grantee and grant may have been allowed to continue without proper oversight.

Between April 19, 2020 and April 26, 2023, NIH conducted an investigation into EcoHealth's compliance with its grant terms. This investigation primarily focused on (1) EcoHealth's late Year 5 Report, (2) an experiment that showed excessive viral growth, and (3) EcoHealth's relationship with the WIV.

1) **April 19, 2020:** Letter from Dr. Lauer to EcoHealth[356]

2) **April 24, 2020:** Letter from Dr. Lauer to EcoHealth[357]

[354] Fauci TI 1, *supra* note 225, at 211-212.
[355] Lauer TI, *supra* note 260, at 22.
[356] Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc., et al (Apr. 19, 2020).
[357] Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc., *et al* (Apr. 24, 2020).

3) **July 8, 2020:** Letter from Dr. Lauer to EcoHealth[358]

In this letter, Dr. Lauer, because of legal issues surrounding NIH's decision to terminate the full grant on April 24, reinstated and then immediately suspended EcoHealth's grant. The suspension was pending EcoHealth's answers to a number of questions regarding activities in and around Wuhan at the time of the outbreak. NIH witnesses testified they agreed with sending this letter.

Dr. Michael Lauer (Nov. 2, 2023)

Q. And did you believe at the time that NIH had the authority to ask these questions -- make these -- let me rephrase. Did you believe at the time that NIH had the authority to make these requests of a grantee?

A. Yes.

Q. Okay. And is that still your opinion, NIH had the authority to make these requests of a grantee?

A. I'm comfortable that, you know, with what was happening at the time, the information I had available at the time, that we followed appropriate processes.[359]

Dr. Lawrence Tabak (Jan. 5, 2024)

Q. Did you agree with sending this letter?

A. I did agree with sending it.[360]

4) **July 23, 2021:** Letter from Dr. Lauer to Dr. Daszak[361]

In this letter, Dr. Lauer first identified that EcoHealth's Year 5 Report was later. Dr. Lauer writes, "[w]e are also writing to notify you that a review of our records for R01AI110964 indicates that EcoHealth Alliance, Inc. is out of compliance with requirements…"[362] Witness testimony indicates that neither NIH nor NIAID identified this late report until this letter was sent.

Dr. Erik Stemmy (Nov. 13, 2023)

[358] Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Peter Daszak, Ph.D*., et. al.,* Pres., EcoHealth Alliance, Inc. (July 8, 2020).
[359] Lauer TI, *supra* note 260, at 53-54.
[360] Tabak TI, *supra* note 83, at 62.
[361] Letter from Dr. Michael Lauer, M.D., Dep. Dir. Extramural Research, Nat'l Insts. Of Health, to Peter Daszak, Ph.D., *et. al*., President, EcoHealth Alliance, Inc. (July 23, 2021).
[362] *Id.*

Q. So this is a July 23rd, 2021, letter from Dr. Lauer to EcoHealth. I don't know if you're -- you are cc'd. Do you recall this letter going -- being sent?

A. Just give me 1 minute to flip through. Yes, I think so.

Q. Were you involved in drafting this letter at all?

A. I don't recall being involved in drafting this letter, no.

Q. Primarily in this letter, in addition to a couple other requests, but Dr. Lauer informs EcoHealth that at this point they were 22 months late on their year 5 progress report. When did you first learn that the year 5 report was late?

A. I don't remember the exact date when I learned this. It may have been with this letter. But because the award was terminated, I wasn't doing the normal sort of oversight work that a program officer would have done, right. Or notifications weren't coming out as well, so --[363]

Dr. Emily Erbelding (Nov. 28, 2023)

Q. While you're flipping through it, this is a letter from Dr. Lauer to EcoHealth from July 23rd, 2021. And in it there's a lot, and it continues to request in order to review the WIV's records validating certain expenditures and monitoring safety and financial specifics. But then also on the second page indicates that EcoHealth has not submitted their year 5 annual report yet.

***

Q. "We are also writing to notify you that a review of our records for R01 indicates that EcoHealth Alliance is out of compliance with requirements to submit the following reports," a financial report and then the Interim Research Performance Progress report.

A. Okay. I see the paragraph you're referring to.

Q. Were you involved at all in the drafting of this letter?

A. No.

[363] Stemmy TI, *supra* note 255, at 127-128.

Q. When did you first learn that the year 5 report was late?

A. I believe I learned of it when it came in, which was about a month after the date on this letter.[364]

Dr. Michael Lauer (Nov. 2, 2023)

Q. In this letter, it's also the first time you notify EcoHealth that they're now 22 months late on their year-five progress report. Is that correct?

A. Yes.

Q. Would that have been consistent with the timing that you testified to earlier, that the interim progress report would've come up with the year-seven funding?

A. So –

Q. Or was it later than what you would normally see?

A. It's later than what we would normally see, but -- okay. Well, I'll answer your question. It's later than what we would normally see.

Q. Okay. When did you learn that the year-five report was late?

A. Shortly before we sent this letter.[365]

On numerous occasions Dr. Daszak held President Trump responsible for the cancellation of the grant.

Dr. Peter Daszak (Nov. 14, 2023)

Q. Did you ever learn any information, either from government officials or nongovernment officials, that connected the statement of intent by then-President Trump to terminate the grant to the decision that was ostensibly made by NIH to terminate the grant?

A. What I heard was that -- look, when President Trump says something, he usually does it. Let's face it. I mean, that's one attribute of President Trump, that when he makes a statement like that he normally follows through.

[364] Erbelding TI, *supra* note 281, at 96-97.
[365] Lauer TI, *supra* note 260, at 66.

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Q. And from what you heard and what you understand, do you believe that it was the HHS Secretary making the decision himself at that point, or through instructions from the President?

A. Well, I think President Trump very clearly stated in that press conference, "We will end it very quickly." And within a week it was ended.

Q. And is this, is your understanding of that formed through public reporting and your sort of connecting the dots, or have people directly told you that?

A. So all of the above.[366]

Notwithstanding Dr. Daszak's testimony, additional testimony regarding the grant cancellation is clear—NIH career public health officials supported and did not doubt the actions undertaken by NIH and Dr. Lauer.

Dr. Michael Lauer (Nov. 2, 2023)

Q. All right. Thank you. I'm going to go back and ask some questions -- a blanket one I think you touched on, but maybe not directly: Would you sign and send a letter if you did not agree with the contents of the letter?

A. No.[367]

Dr. Hugh Auchincloss (Dec. 20, 2023)

Q. I want to first start by, as you know, NIH Office of Extramural Affairs started compliance efforts with regard to EcoHealth in April of 2020. Every letter sent by them was sent by Mike Lauer, who heads that office. When he testified in front of us, he said that he would not sign and send a letter that he disagreed with. Do you have any reason to doubt that assertion?

A. None.[368]

Dr. Lawrence Tabak (Jan. 5, 2024)

[366] Daszak TI, *supra* note 253, at 203-204.
[367] Lauer TI, *supra* note 260, at 55.
[368] Auchincloss TI, *supra* note 233, at 147-148.

Q. So understanding there wasn't, if any, involvement prior to 2020, I'm going to shift ahead to the 2020 to present timeframe as it pertains to EcoHealth and start with one question. We had a similar interview with Dr. Lauer, and he testified at that interview that he would not sign or send a letter that he disagreed with. Do you have any reason to doubt that assertion?

A. I have no doubt at all about that.[369]

Dr. Francis Collins (Jan. 12, 2024)

Q. Moving into 2020. Before we start with individual letters, we asked Dr. Lauer and he testified that he would not sign or send a letter that he disagreed with. Do you have any reason to doubt that assertion?

A. No.

Q. Do you agree with every enforcement action the NIH took against EcoHealth?

A. Yes.[370]

Dr. Fauci was the only official at the Director or Deputy Director level the Select Subcommittee interviewed who was evasive regarding Dr. Lauer's integrity.

Dr. Anthony Fauci (Jan. 8, 2024)

Q. Okay. I want to shift to a time period a little closer -- it's still 2020, but it's at least closer than 2016 -- and ask a blanket question first. Dr. Lauer testified that he would not sign or send a letter that he disagreed with. Do you have any reason to doubt that assertion?

A. He would not sign –

Q. Or send a letter that he disagreed with.

A. I can't speak for him.[371]

As discussed above, Mr. Meadows instructed HHS and NIH to terminate or suspend the grant to EcoHealth because of concerns that arose regarding the WIV and compliance. This instruction resulted in a multi-year effort to investigate and oversee EcoHealth's actions, including an investigation led by Dr. Lauer with the support of NIH leadership—notably Dr.

[369] Tabak TI, *supra* note 83, at 51.
[370] Collins TI, *supra* note 219, at 145.
[371] Fauci TI 1, *supra* note 225, at 210.

Collins and Dr. Tabak. Contrary to Dr. Daszak's testimony and public reporting, the actions levied against EcoHealth were not political, but instead supported by facts and evidence and executed by career public health officials.

FINDING:	Dr. Anthony Fauci Played Semantics with the Definition of Gain-of-Function Research.

Throughout the COVID-19 pandemic, many scientists and government officials categorically denied that taxpayer funds were used for gain-of-function research in Wuhan at the WIV. These assertions rested on semantics and the misapplication of understood definitions.

On May 11, 2021, Dr. Fauci testified before the U.S. Senate Committee on Health, Education, Labor, and Pensions [hereinafter "HELP"].[372] At this hearing, Senator Rand Paul (R–Ky.) asked Dr. Fauci if gain-of-function research was occurring with NIH funding at the WIV. Dr. Fauci categorically denied it three times.

May 11, 2021 Hearing Before Senate HELP

Senator Paul.	Dr. Fauci, do you still support funding of the – NIH funding of the lab in Wuhan?
Dr. Fauci.	Senator Paul, with all due respect, you are entirely and completely incorrect that the NIH has not ever and does not now fund gain-of-function research in the Wuhan Institute of Virology.
***	
Senator Paul.	Will you, in front of this group, categorically say that the COVID-19 could not have occurred through serial passage in the laboratory?
Dr. Fauci.	I do not have an accounting of what the Chinese may have done, and I am fully in favor of any further investigation of what went on in China. However, I will repeat again, the NIH and NIAID categorically has not funded gain-of-function research to be conducted in the Wuhan Institute of Virology.
***	
The Chair.	I will allow you to respond to that, and then we will move on.

[372] An Update From Federal Officials on Efforts to Combat COVID-19: Hearing Before Sen. Comm. on Health, Education, Labor, and Pensions, 117th Cong. (May 11, 2021).

Dr. Fauci.	Yes. I mean, I just wanted to say, we – I do not know how many times I can say it, Madam Chair. We did not fund gain-of function research to be conducted in the Wuhan Institute of Virology.[373]

Dr. Fauci's testimony was, at a minimum, misleading. As established above, at the time of Dr. Fauci's testimony senior NIH officials and the NIH website defined gain-of-function research as "a type of research that modifies a biological agent so that it confers a new or enhanced activity to that agent." Further, witness testimony and a plain reading of EcoHealth's research conducted at the WIV using U.S. taxpayer dollars confirm it facilitated an experiment that conveyed new or enhanced activity to a pathogen—thus, satisfying the definition of gain-of-function research.

Dr. Fauci, during his transcribed interview before the Select Subcommittee, stood by his Senate HELP testimony.

Dr. Anthony Fauci (Jan. 8, 2024)

Q. When you talk about this issue, this broader issue of gain-of-function and Wuhan Institute of Virology, publicly -- for example, the high-profile exchange with Senator Rand Paul --

A. Right.

Q. -- and if you say that NIH, quote, "has not ever and does not now fund gain-of-function research in the Wuhan Institute of Virology," is this layman's definition the definition that you are talking about in those occasions?

A. No.

Q. Great. What would you be talking about in those situations?

A. What I was referring to when Senator Paul asked me and I repeated multiple times that we were not doing gain-of-function research, no -- I said that the NIH sub-award to the Wuhan Institute was not to do gain-of-function research. I was referring specifically to the operative definition of "gain-of-function" at the time, which is the P3CO framework. And the P3CO framework is a policy and a framework that came out of a policy guidance from 3 years of discussions led by OSTP, the National Academies of Sciences, and multiple scientific working groups that came out with a very precise definition. And the precise definition was: any experiment that is

[373] *Id.*

reasonably anticipated to result in the enhancement of a -- and by "enhancement," it is meant an increase in the transmissibility and/or the pathogenesis of a PPP. And what a PPP is is a potential pandemic pathogen. So if you enhance it, it's referred to as "ePPP." So then you ask the question, what is a PPP? And by the regulatory definition, it is the following: It is a pathogen that is likely to be highly transmissible and spread widely in a population and a pathogen that likely will cause a high degree of morbidity and mortality in humans. So, when I was asked the question, did the grant that was a sub-award to Wuhan fund experiments that were enhanced PPP, that is what I was referring to when I said we do not fund gain-of-function -- gain-of-function according to the strict definition, which I refer to as the operative definition of "gain-of-function." So, when someone asks me, as a scientist, are you doing gain-of-function, is that gain-of-function, I always apply it to the operative definition of "gain-of-function."

Q. That is very helpful. Thank you for drawing that distinction. And at the time of that exchange, it was the P3CO framework. There was also a time, I think from 2014 to 2017, when the gain-of-function moratorium was the operative policy.

A. Right.

Q. So a similar analysis, I assume, would've been the case for that –

A. Right.

Q. -- period of time.

A. Yes.[374]

Dr. Anthony Fauci (Jan. 8, 2024)

Q. I want to introduce the year 5 progress report as majority exhibit 18. And in the nature of time, it's a long report, so I'd ask you not to read the whole report, but I'm going to draw your attention to a discrete paragraph. It's on page 15 under aim 3.1.

***

Q. And I believe, and Dr. Tabak has confirmed that in his letter he is referring to the experiment outlined in this paragraph. And I'm going to -- you have it in front of you, but I'm going to read it in kind of

[374] Fauci TI 1, *supra* note 225, at 47-48.

layman's terms so it's comprehendible. But, in essence, it says that mice were infected with four strains of SARS-related coronaviruses with different spike proteins, including full-length recombinant virus of 4 SARS-related WIV 1 and 3 chimeric viruses, with the backbone of WIV 1 and the spike proteins from three other bat coronaviruses. So that's what we were just discussing. All four of the viruses caused lethal infection in human ACE2 transgenic mice, but the mortality rate varied among the four groups. Fourteen days post-infection, five out of the seven mice infected with just the WIV 1 backbone remained alive, while only two out of eight mice infected with the SHC014 chimera survived. And the paragraph ends with, "These results suggest that the pathogenicity of SHC014 is higher than other tested bat SARS-related coronaviruses in transgenic mice that express human ACE2." I'll give you a minute to read the full version in the progress report. I know I kind of summarized it.

A. [Reviewing.] Yeah.

Q. So to me, it sounds like seven mice infected with the full-length WIV 1; five survived. Eight mice infected with a chimera of WIV 1 and SHC014 and two survived. Is that your understanding as well?

A. That's what it says, yeah.

Q. This to me sounds like the experiment that EcoHealth conducted by creating a chimera increased the pathogenicity of the underlying virus. Is that fair?

A. The underlying virus is WIV.

Q. Correct.

A. And the spike that they put on indicated that the virus was more pathogenic than the WIV.

Q. Correct. Is that right? So by replacing the WIV 1 spike with the SHC spike –

A. Yes, yes. But, again, you got to put it into context because, again, these viruses, when you -- if you -- are you hearkening back to the definition of whether –

Q. I'm getting there.

A. Yeah, but then let's go there, okay? The fact is that what was built into the scope of the conditions was that if you do get an increase in viral load or pathogenesis, you've got to report it or reevaluate it, but it still doesn't change the underlying premise that this is not a PPP. That's the point. That's the conclusion -- that's the confusion people get. By the operative definition of gain-of-function of concern, even with this, this is merely an added going the extra mile that if something like this happens you stop and you look at it and discuss whether or not to go forward, et cetera. And, to my understanding, that even if you do that, this still doesn't change that you're not dealing with a virus that's very likely to lead to widespread transmission, et cetera, et cetera. So it doesn't change the definition or the operative guideline for this experiment, but it tells you, you should report this, because that was part of the fail-safe.

Q. And I don't disagree with you that it's not an ePPP –

A. Yeah, right.

Q. -- and it doesn't fall under the P3CO framework. What I think we're trying to understand is this was submitted, I mean, well, late, but the work was conducted during 2018 for the fiscal year 2018 to 2019 and the year 5 progress report. At that time, this definition of gain-of-function was still live on the website of enhancing a biological agent. And I guess what I'm trying to understand, and the minority talked about it too, is you said what your intent was with Senator Paul, that when you said NIH does not now and has not ever funded gain-of-function research in Wuhan was that you meant to say or you intended ePPP research.

A. I said that before and I'll repeat it again. When I talk about gain-of-function, I talk about -- a gain-of-function of concern -- I am talking about the operative definition of gain-of-function of concern, which for me is the P3CO that we've discussed multiple times.

Q. And I agree, again, agree that this experiment did not meet the P3 definition. Would you agree that it meets that broad definition of gain-of-function that was on NIH's website when this research was conducted?

A. Again, I don't use the terminology "gain-of-function" because it can be very confusing, which was the reason why we went through 3 years of discussion to avoid the kind of confusion that we're going to get into now if we start going back and forth about this. That was the whole reason for 3 years of deliberation to establish a regulatory guideline based on a guiding policy that led to a framework. So,

regardless of how you slice it, when I spoke to -- when I responded to Doctor -- to Senator Paul, I was referring to the gain-of-function research of concern as defined by the P3CO framework.

Q. My last question. That hearing was May 11th, 2021. When you testified, like -- again, I apologize, but if I was a general C-SPAN watcher or watching the news afterwards it obviously became a big deal, and I went and I googled NIH gain-of-function research, this is what would come up. Do you think you could have -- like, you knew that you meant ePPP.

A. Yes.

Q. Do you think you could have been more specific in your answer?

A. Well –

***

A. I think -- I think in terms of 3PCO, and that's embedded in my mind, he didn't appreciate what gain-of-function according to the regulatory guidelines are. I was speaking in that term. So he was thinking of a different thing. When I spoke to him, I'll stand by my statement that when I said we do not do gain-of-function I was referring to gain-of-function of concern according to the 3PCO guideline, done, full stop.

***

Q. The last thing I'll say is we interviewed Dr. Tabak on Friday -- it's been a long weekend -- and we asked him a similar question. "What's described in the EcoHealth year 5 progress report would fit the definition -- the broad definition of gain-of-function research?" And he answered, "The generic, broad description of what gain-of-function is, yes." Would you agree with Dr. Tabak?

A. You know, again, we're going in circles, because it's going to get the same confusion that the chairman was just talking about.

Q. I'm –

A. Because then, if I say yes, then, "Ah, yes, he says it was gain-of-function." It is not gain-of-function of concern that is associated with the regulatory operative definition of gain-of-function.

Q. No. And I'm entirely willing to stipulate that and stipulate that it didn't need to go through the P3CO and it didn't meet the definition of ePPP. And I'll end on this, and if it's the same answer it's the same answer. But we've asked Dr. Auchincloss this question. We've asked Dr. Tabak this question. Both have said that it meets the definition, the broad definition of gain-of-function research. I'm not trying to catch you in a trap. I'm not trying to catch you –

A. But the thing is I have been living a life over the last few years of getting total distortion of things that I've said and done, and you know that. So if you want me to –

***

Q. You don't need to answer again. I'll take that what you meant is what –

A. Right.

Q. And I agree that that is what you meant. I'm not trying to go against that. I'm just -- when people read things in black and white and words are said, it's hard to distinguish sometimes.

A. Yes.

Q. Our hour is up, and we can go off the record. Our day is up too.[375]

[Whereupon, at 6:57 p.m., the interview was recessed, to reconvene at 10:00 a.m., Tuesday, January 9, 2024.]

Dr. Fauci testified that when he testified before the Senate, he was using the "operative" definition of gain of function. However, that was not the definition of that term used by the NIH at that time. Unfortunately, the website containing that definition was unceremoniously removed and that definition deleted the same day the EcoHealth experiment was reported to Congress. Dr. Fauci's testimony to Senator Paul misled the public regarding NIH funding of gain-of-function research at the WIV.

FINDING:	The U.S. National Institutes of Health and National Institute of Allergy and Infectious Diseases Granted U.S. Taxpayer Funds to the Chinese People's Liberation Army.

[375] Fauci TI 1, *supra* note 225, at 219-226.

On April 13 2020, Mr. Handley prepared a background document outlining NIAID's interaction with China and its current relationship with various grantees.[376] This document was presented to Dr. Fauci.[377] As an illustrative example of the lack of vetting of both foreign laboratories and collaborators, this document lists at least three grants that include Dr. Yusen Zhou—a known CCP member and PLA officer—as a collaborator.[378]

RATIONAL DESIGN AND EVALUATION OF NOVEL MRNA VACCINES AGAINST MERS-COV (AI137472) , *NEW YORK BLOOD CENTER,*
Collaborators : Zhou, Yusen, Beijing Institute of Microbiology and Epidemiology, CHINA;
A NOVEL AND EFFECTIVE NANOBODY TO PREVENT AND TREAT ZIKA VIRUS INFECTION (AI137790) , *NEW YORK BLOOD CENTER,*
Collaborators : Zhou, Yusen, Beijing Institute of Microbiology and Epidemiology, CHINA;

FOR NIAID USE ONLY

STRUCTURE-BASED DESIGN OF CORONAVIRUS SUBUNIT VACCINES (AI139092), *NEW YORK BLOOD CENTER,*
Collaborators: Zhou, Yusen, Beijing Institute of Microbiology and Epidemiology, CHINA;

FINDING: Senior National Institute of Allergy and Infectious Diseases Leadership Fostered an Environment That Promoted Evading the Freedom of Information Act.

FOIA establishes a statutory right of public access to Executive Branch information in the federal government.[379] FOIA provides that any person has a right, enforceable in court, to obtain access to federal agency records subject to the Act, except to the extent that any portions of such records are protected from public disclosure by one of nine exemptions.[380]

In the process of seeking official COVID-19 related documents, the Select Subcommittee discovered documents suggesting senior officials in Dr. Fauci's office flagrantly used deceptive tactics to prevent their e-mails and correspondences from being discovered as responsive to FOIA requests.

On June 4, 2021, Mr. Folkers intentionally misspelled "EcoHealth" as "Ec~Health."[381]

[376] Memorandum by F. Gray Handley, Associate Dir. For International Affairs, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Apr. 13, 2020).
[377] *Id.*
[378] *Id.*
[379] 5 U.S.C. § 552 (2018); *see also, John Doe Agency v. John Doe Corp*., 493 U.S. 146, 150 (1989) ("This Court repeatedly has stressed the fundamental principle of public access to Government documents that animates the FOIA.").
[380] *See* 5 U.S.C. § 552 (a)(3), (a)(4)(B), (b), (c).
[381] E-Mail from Gregory Folkers, Chief of Staff, Nat'l Inst. of Allergy & Infectious Diseases, to Courtney Billet, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, *et al.* (June 4, 2021, 9:36 PM).

From: Folkers, Greg (NIH/NIAID) [E] [redacted]
Sent: Friday, June 4, 2021 9:36 PM
To: NIAID OD AM [redacted] Billet, Courtney (NIH/NIAID) [E] [redacted] Routh, Jennifer (NIH/NIAID) [E] [redacted] Stover, Kathy (NIH/NIAID) [E] [redacted]
Subject: ASF and all this may come up in interviews

In the recent Bulletin of the Atomic Scientists article, we have this quote

"It is clear that some or all of this work was being performed using a biosafety standard—biosafety level 2, the biosafety level of a standard US dentist's office—that would pose an unacceptably high risk of infection of laboratory staff upon contact with a virus having the transmission properties of SARS-CoV-2…."

My understanding is that human coronaviruses including sarbecoviruses are routinely worked at in BSL-2 around the world as are many other viruses that can cause problems for people. The BSL level designation is decided by each country and is not related to perceived pandemic potential but largely to risk to the BSL workers.

For example, BSL-4 designation generally means deadly virus, infectious by aerosol, no vaccine against it, and no treatment for it. So, although rabies is 100% fatal in humans, it can be prevented by a vaccine and prevented by a post exposure serum, and (probably if not totally) not infectious by aerosol, thus it is BSL-2 even though among the deadliest of human viruses. Working with non-human coronaviruses at BSL-2 is widespread since these viruses are not known to infect humans.

David, Alan and others may have additional thoughts.

Attached is a fact sheet that I think comes from Ec~Health

Again, in an original email from June 7, 2021, Mr. Folkers intentionally misspelled "Andersen" as "anders$n"—an email Dr. Morens eventually forwarded to his Gmail.[382]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[382] E-Mail from Gregory Folkers, Chief of Staff, Nat'l Inst. of Allergy & Infectious Diseases, to David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (June 16, 2021, 1:03 PM).

Date: Wed, 16 Jun 2021 1:10:19 PM -0400
Sent: Wed, 16 Jun 2021 1:03:57 PM -0400
Subject: FW: anders$n
From: "Morens, David (NIH/NIAID) [E]" [redacted]
To: David Morens [redacted]
Attachments: image001.gif; image002.jpg

David

David M. Morens, M.D.
CAPT, United States Public Health Service
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[redacted]

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Again, on June 25, 2021, Mr. Folkers intentionally misspelled "gain-of-function" to be "g#in-of-function."[383]

[383] E-Mail from Greg Folkers, Chief of Staff, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (June 25, 2021, 11:25 AM).

On Jun 25, 2021, at 11:25, Folkers, Greg (NIH/NIAID) [E] <[redacted]> wrote:

David,

The WSJ editorial below argues that the presence of CGG-CGG is evidence that SARS-CoV-2 is the result of g#in-of-function research. What do you and the virologists in your orbit make of this? What is the best argument that this is probably not the case?

The intentional misspelling of these key words makes the e-mail more difficult to identify via a keyword search to fulfill a FOIA request. The terms "Andersen," "EcoHealth," and "gain-of-function" were frequently key words searched in many FOIA requests from the media and others during the pandemic response.

Further, the apparent intentional misspellings of "Anders$n," "Ec~Health," and "g#in-of-function" cannot be reasonably explained as typographical errors. The added symbols could not be a slip or minor keyboard mistake. None of the "$," "~", and "#" are directly adjacent to either letter they are intended to replace, and to place the symbols in a document, the additional "shift" key must be pressed. These actions are indicative of a culture of avoiding accountability and transparency by the unelected public health bureaucracy.

FINDING:	A National Institute of Allergy and Infectious Diseases Freedom of Information Act Official Apparently Aided Others in Efforts to Evade the Freedom of Information Act.

According to documents, Ms. Moore assisted other employees regarding how to avoid producing responsive documents or ensuring documents are not recoverable.

On February 25, 2021, Dr. Morens stated that he learned tricks to evade the FOIA from Ms. Moore "who heads our FOIA office," and she "also hates FOIAs."[384]

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[384] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Gregory Keusch, M.D. (Feb. 25, 2021, 11:25 AM).

-----Original Message-----
From: Morens, David (NIH/NIAID) [E] [redacted]
Sent: Thursday, February 25, 2021 12:06 PM
To: Keusch, Gerald T. [redacted]
Cc: Peter Daszak [redacted]
Subject: Re: Briefing Tony

It's more in the line of govt secret, but too comp;licated to explain in an email. But I learned the tricks last year from an old friend, Marg Moore, who heads our FOIA office and also hates FOIAs.

Incidentally, Tony and I and a few other people here all got a huge FOIA yesterday seeking any and all documents, emails, etc., that mention the words "Wuhan Institute" or "WIV". It appears that this comes from folks tied to politics, who want specifically to know about anything NIH has had to do with WIV, or any scientists working with WIV. The original request was I think far broader, but we negotiated it down to just those two terms. You names will not show up in this FOIA, at least not from my info. d

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david..... PS, I will be on Public Health Service deployment from 10 December 2020 until 23 January 2021. During this time I will have limited access to email and phone contact. Ty, dmm

On February 24, 2021, Dr. Morens again discussed how he learned specific tactics from "our foia lady" on how to work around FOIA regulations, avoid transparency and accountability, and "make emails disappear after i am foia'd but before the search starts."[385] Dr. Morens concluded "I think we are all safe."[386]

On Feb 24, 2021, at 9:21 AM, David Morens <dmmorens@gmail.com> wrote:

EHA_0005319

You are right, i need to be more careful. However, as i mentioned once before, i learned from our foia lady here how to make emails disappear after i am foia'd but before the search starts, so i think we are all safe. Plus i deleted most of those earlier emails after sending them to gmail. D

Sent from my iPhone
David M Morens
OD, NIAID, NIH

[385] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Gerald Keusch. M.D., *et al*. (Feb. 24, 2021, 9:21 AM).
[386] *Id.*

During a public hearing, Dr. Morens testified that these conversations were a "joke" and stated that Ms. Moore "didn't give me advice about how to avoid FOIA."[387]

Considering the conflict between Dr. Morens' emails and his testimony, the Select Subcommittee sought to question Ms. Moore regarding knowledge of these issues.

On May 31, 2024, the Select Subcommittee attempted to arrange a voluntary transcribed interview to obtain Ms. Moore's testimony. The Select Subcommittee only began the process of scheduling a transcribed interview after she did not reply to several attempts by Select Subcommittee staff to schedule an informal briefing by phone.[388] Ms. Moore eventually retained personal counsel.[389]

Select Subcommittee staff and Ms. Moore's personal counsel engaged in negotiations to facilitate a voluntary interview.[390] The Select Subcommittee offered numerous accommodations, including limiting the scope of the interview.[391] On August 5, 2024, Ms. Moore, via her counsel, formally refused to testify.[392]

Subsequently, the Select Subcommittee issued a subpoena for Ms. Moore for a deposition in Washington, D.C. on October 4, 2024.[393] The Select Subcommittee asked Ms. Moore if she had "any conversations with Dr. David Morens regarding his obligations pursuant to the Freedom of Information Act or document retention laws and policies?"[394] In response, Ms. Moore invoked her right against self-incrimination pursuant to the Fifth Amendment of the Constitution.[395]

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[387] A Hearing with the National Institute of Allergy and Infectious Diseases Senior Scientific Advisor, Dr. David Morens: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong, 2, (May 22, 2024) [hereinafter "Morens Hearing"].
[388] Letter from Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, to Margaret Moore (Sept. 30, 2024).
[389] *Id.*
[390] *Id.*
[391] *Id.*
[392] *Id.*
[393] Wenstrup Letter, *supra* note 388.
[394] *See,* Deposition of Maragret Moore (Oct. 4, 2024).
[395] *Id.*

The Efficacy, Effectiveness, and Transparency of the Use of Taxpayer Funds and Relief Programs to Address the Coronavirus Pandemic, Including Any Reports of Waste, Fraud, or Abuse

The COVID-19 pandemic left a detrimental impact on small businesses across the U.S., resulting in business closures, product shortages, and widespread job losses. Americans faced instability in their daily lives prompting action by Congress to stabilize the economy and providing critical resources to affected individuals, businesses and communities.

Congress passed the CARES Act, a $2.2 trillion dollar relief package designed to address the economic impacts on small business and individuals. This legislation created and extended programs such as PPP, EIDL, and enhanced UI benefits. The CARES Act also established the PRAC to provide independent oversight of pandemic relief spending by coordinating IGs whose agencies administer pandemic relief programs.

The unprecedented scale and lack of transparency in COVID-19 pandemic relief programs exposed vulnerabilities for waste, fraud, and abuse. Reports of improper payments, fraudulent claims, and misuse of funds have raised alarming concerns about where these funds are going and who they are going to.

Federal agencies must do better to prepare for future public health crises to ensure accountability and transparency in agencies to prevent waste fraud and abuse in emergency relief programs.

I. The Paycheck Protection Program

On March 27, 2020, President Trump signed the CARES Act, which created PPP under section 1102 7(a) of the Small Business Act.[396] PPP provided essential relief for small businesses, individuals, and nonprofit organizations by offering loans that could be forgiven if the funds were used in accordance with criteria enumerated in the legislation.

Rollout of the Payment Protection Program

From the beginning of the COVID-19 pandemic, there was unprecedented public demand for relief loans, especially for small businesses. A month after PPP was established, individual and business applicants were granted $349 billion in taxpayer funded loans.[397] On April 24, 2020, Congress allocated another $310 billion to PPP—in addition to the original $659 billion—through the Health Care Enhancement Act.[398]

[396] Coronavirus Aid, Relief, and Economic Securities (CARES) Act, Pub. L. No. 116-136, 134 Stat. 281 (2020) [hereinafter "CARES Act"].
[397] Stolen Taxpayer Funds: Reviewing the SBA and OIG Reports of Fraud in Pandemic Lending Programs: Hearing Before H. Comm. On Small Businesses, 118th Cong. 1, (July 13, 2023) (Testimony of Hannibal "Mike" Ware, Inspector General).
[398] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-136, 134 Stat. 620 (2020).

On June 5, 2020, the PPP Flexibility Act modified the program by extending time under which recipients had to spend funds from eight weeks to twenty-four weeks.[399] While this granted new flexibilities to loan recipients, it also resulted in greater potential for error and increased opportunities for fraud and improper payments.

On December 27, 2020, Congress extended PPP through the Economic Aid to Hard-Hit Small Business, Nonprofits and Venues Act in the Consolidated Appropriations Act, 2021.[400] Small businesses financially affected by the COVID-19 pandemic received continued assistance through March 31, 2021, equaling an additional $147.5 billion in program funding, increasing total funding to $806.5 billion.[401]

ARPA provided an additional $7.2 billion in PPP funding, increased the total funding to $813.7 billion.[402] President Biden signed the legislation, which extended the deadline to apply for PPP loans to May 31, 2021.[403]

The rapid rollout of pandemic relief funds and lack of adequate systems to determine eligibility and distribute assistance paved the way for large amounts of improper payments and fraud. The SBA IG estimated the U.S. taxpayers lost $64 billion in fraud attributable to PPP alone.[404]

Structure of the Payment Protection Program

PPP loans were rapidly disbursed by SBA following the program's establishment. To qualify for a PPP loan, of which applicants had to self-certify their eligibility, applicants needed to have less than 500 employees, been operational as of February 15, 2020, and certify the funds would be used for specific purposes, such as payroll expenses, interest payments, rent, or utilities.[405] Under the CARES Act, 60 percent of funds received had to be allocated for payroll costs and other eligible employee expenses to qualify for loan forgiveness.[406]

Initial Oversight of PPP Loans

In June 2020, GAO released its first bimonthly report which revealed that—because the loan application process was essentially based on merit and self-reporting—the program was

[399] Robert J. Dingler & Sean Lowry, CONG. RESEARCH SERV., R46397, SBA Paycheck Protection Program (PPP) Loan Forgiveness: In Brief (last updated Sept. 3, 2020).
[400] *Id.*
[401] *Id.* (last updated Apr. 23, 2021).
[402] *American Rescue Plan Expands PPP Eligibility*, PYA (Mar. 31, 2021).
[403] Grace Segers, *Biden signs PPP extension into law, moving application deadline to May 31*, CBS NEWS (Mar. 30, 2021).
[404] Dan Nanz, *How the FBI is Combating COVID-19 Related Fraud*, FBI SPRINGFIELD PRESS OFFICE (Jan. 12, 2024).
[405] PPP Borrower Information Fact Sheet, U.S. TREASURY DEP'T.
[406] Press Release, U.S. Small Business Admin., Joint Statement by SBA Administrator Jovita Carranza and U.S. Treasury Secretary Steven T. Mnuchin Regarding Enactment of the Paycheck Protection Program Flexibility Act (June 8, 2020).

susceptible to fraudulent claims.[407] Eligibility for receiving a PPP loan was based on the claimant self-asserting their PII without verification by the SBA. This lenient approach to distributing federal relief funds opened the door for exploitation, with some applicants fraudulently inflating payroll costs to secure larger loans, misrepresenting their number of employees to falsely appear eligible, and certifying that the funds would be used for allowable expenses while diverting them for personal use.[408]

FINDING:	The Paycheck Protection Program Was Rife with Fraudulent Claims Resulting in at Least $64 Billion of Taxpayers' Dollars Lost to Fraudsters and Criminals.

PPP was susceptible to many forms of waste, fraud, and abuse due to its rapid implementation and reliance on self-verification by applicants. The most common ways this program was exploited was through inflated payroll costs, misrepresenting employee numbers, misuse of loan proceeds, submitting multiple applications, creating false certifications, committing identify theft, loan stacking, and fake documentation.[409]

Fraudulent Loan Applications

PPP fraud became one of the most accessible avenues for exploiting pandemic relief funds. One of the largest PPP fraud cases prosecuted by DOJ involved six individuals who conspired and submitted 75 fraudulent loan applications.[410] Using fake bank records and fabricated federal tax forms, these defendants managed to secure $20 million in federal PPP funds by inflating employee numbers and falsifying payroll amounts of their loan applications.[411] Like many other cases, these individuals engaged in additional illegal activities, including cashing more than 1,100 fake PPP paychecks amounting to more than $3 million that was supposed to go towards employee payroll.[412]

In another case prosecuted by DOJ, a California man was convicted for submitting fraudulent applications to obtain PPP loans.[413] By simply providing false information, he secured $27 million in forgivable loans.[414] He claimed his company had more than 100 employees with an average monthly payroll of $400,00.[415] After receiving $3 million in taxpayer money, he used the funds for personal expenses, including cash withdrawals, payments on personal credit cards, and transfers to other personal and business accounts under his control.[416] The individual now

[407] GAO, GAO-20-625, COVID-19 OPPORTUNITIES TO IMPROVE FEDERAL RESPONSE AND RECOVERY EFFORTS (June 2020).
[408] Ken Dilanian & Laura Strickler, *'Biggest fraud in a generation': The looting of the Covid relief plan known as PPP,* NBC NEWS (Mar. 28, 2022).
[409] GAO, GAO-23-105331, COVID RELIEF FRAUD SCHEMES AND INDICATORS IN SBA PANDEMIC PROGRAMS (May 2023).
[410] Press Release, DOJ, Leader of $20M COVID-19 Relief Fraud Ring Sentenced to 15 Years (Oct. 3, 2023).
[411] *Id.*
[412] *Id.*
[413] Press Release, DOJ, Man Convicted for $27 Million PPP Fraud Scheme (Mar. 29, 2022).
[414] *Id.*
[415] *Id.*
[416] *Id.*

faces up to 30 years in prison for charges of bank fraud, making false statements, and money laundering.[417]

Fraudsters Using Unverified Social Security Numbers

Since opening investigations, PRAC identified 69,323 questionable SSNs used to obtain $5.4 billion from PPP and EIDL programs.[418] Fraudsters used SSNs that were either stolen from real or dead individuals or completely fabricated to create fake identities, impersonate legitimate businesses, and submit multiple loan applications under multiple identities.[419] Using fake SSNs allowed individuals to bypass background checks, receive funds illicitly, and launder money through transfers, cash withdrawals, or high-value purchases.[420]

One specific investigation from DHS resulted in the conviction and five-year prison sentence of a Florida man for fraudulently obtaining two Florida identification cards to apply for three PPP loans using the identities of two separate victims.[421] He received approximately $150,000 in PPP loans.[422] Further investigation by the IRS indicated that the same Florida man also submitted eight fraudulent tax returns using the stolen identities of six victims unrelated to COVID-19 relief funds.[423]

U.S. Agencies IGs continue to investigate PPP fraud and other pandemic relief funds. Many investigations have led officials to more serious organized criminals. As of August 2023, the federal government charged 3,195 defendants for offenses related to PPP fraud and seized more than $1.4 billion in relief funds, many of them from PPP fraud.[424] U.S. Attorney Offices and dozens of federal, state, and local law enforcements agencies have also opened their own investigations.[425]

FINDING:	The U.S. Small Business Administration Did Not Properly Define Critical Internal Roles and Responsibilities and Failed to Provide Actionable Guidance to External Stakeholders to Manage Fraud Risk and Combat Paycheck Protection Program Abuse.

[417] *Id.*
[418] Federal Pandemic Spending: A Prescription for Waste, Fraud, and Abuse: Hearing Before H. Comm. On Oversight and Accountability, 118th Cong. 1, (Feb. 1, 2023) (Statement of Michael E. Horowitz, Chair, Pandemic Response Accountability Comm. Inspector General, DOJ).
[419] PANDEMIC RESPONSE ACCOUNTABILITY COMMITTEE, PRAC-2023-02, FRAUD ALERT: PRAC IDENTIFIES $5.4 BILLION IN POTENTIALLY FRAUDULENT PANDEMIC LOANS OBTAINED USING OVER 69,000 QUESTIONABLE SOCIAL SECURITY NUMBERS (Jan. 30, 2023).
[420] *Id.*
[421] New Release, Homeland Security Investigations, Florida Man Sentenced for 'PPP' Fraud, Identity Theft (Mar. 19, 2024).
[422] *Id.*
[423] *Id.*
[424] Madeleine Ngo, *Over 3,100 Charged With Pandemic Relief Fraud, Justice Dept. Says*, THE N.Y. TIMES (Aug. 23, 2023).
[425] Examining Federal Efforts to Prevent, Detect, and Prosecute Pandemic Relief Fraud to Safeguard Funds for All Eligible Americans: Hearing Before Select Subcomm. on the Coronavirus Crisis, 117th Cong., (June 14, 2022) (Statement of Michael E. Horowitz, Chair, Pandemic Response Accountability Committee, Inspector General, DOJ).

SBA lacked a well-structured organizational framework with clearly defined roles, responsibilities, and processes to manage and handle potentially fraudulent PPP loans across the program.[426] SBA did not establish a sufficient fraud risk framework, and therefore lenders had little to no information on how to handle PPP fraud or recover funds that were already disbursed that were suspected fraud.[427] Even though lenders continually stressed the necessity of specific guidance from SBA to ensure they were meeting the agency's requirements, none was provided.[428] SBA was one of many federal agencies that did not implement internal controls, fraud prevention measures, or adequate financial and risk management capabilities even though they were required by law.[429]

SBA Did Not Properly Define and Assign Roles and Responsibilities in Combating PPP Fraud

The SBA did not clearly designate points of contact for handling various aspects of fraud in the program and never defined their roles and responsibilities.[430] During a SBA IG investigation, the IG found the SBA's Office of Capitol Access and Office of General Counsel were in supportive roles and involved in only a portion of fraud risk effort instead of being fully integrated into that effort.[431] They also found that SBA pointed to their publicly available "Frequently Asked Questions" site and interim final rules for many questions that were asked. These documents only contained general statements on SBA preventing fraud waste and abuse within the PPP.[432]

During SBA IG's investigation, they interviewed employees of offices within SBA including the Office of Financial Assistance. An official from that office said they did not have a formal internal process for handling potentially fraudulent PPP loans and referred them to the Office of Financial Program Operations, an office not associated with the SBA.[433] When IG officials met with the Office of Financial Program Operations, an official told them the PPP guidance did not address fraud and referred them back to the Office of Financial Assistance for formal processes.[434]

SBA Lacked Specific Guidance to Lenders Regarding PPP Fraud Schemes

Lenders that distributed PPP loans to "qualifying" applicants lacked clear guidance from the SBA on how to handle PPP fraud or recover funds obtained fraudulently from scammers.[435] Instead, the SBA assumed lenders already established and implemented industry regulations

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[426] *See generally*, U.S. SMALL BUSINESS ADMIN., REPORT 22-13, SBA'S HANDLING OF POTENTIALLY FRAUDULENT PAYCHECK PROTECTION PROGRAM LOANS (May 26, 2022).
[427] *Id.*
[428] *Id.*
[429] *Id.*
[430] *Id.*
[431] *Id.*
[432] *Id.*
[433] *Id.*
[434] *Id.*
[435] *Id.* (Lenders that distributed PPP loans to "qualifying" applicants lacked a clear guidance from the SBA on how to handle PPP fraud or recover funds obtained fraudulently from criminals).

regarding fraud. As a result, the SBA blamed financial institutions and lenders rather than taking responsibility for not developing and communicating actionable guidance to manage PPP fraud risk.[436]

Prior to the COVID-19 pandemic, lenders had little to no communication with OIG investigative agencies.[437] However, SBA OIG received a significant volume of requests from lenders and financial institutions on how to handle potentially fraudulent PPP loans, with PPP fraud hotline complaints exceeding 54,000.[438] Providing lenders with sufficient information and guidance on how to address PPP fraud would have established a foundation for addressing fraud and would have prevented billions of taxpayer's dollars from going to criminals.

[436] *Id.*
[437] *Id.*
[438] *Id.*

II. Enhanced Unemployment Insurance

In the early days of the COVID-19 pandemic, Congress and the Executive Branch fast-tracked emergency relief packages aimed at stabilizing the economy and providing crucial support to individuals and businesses. States quickly issued stay-at-home orders because of overcrowded hospitals and a rising mortality rate, leading to widespread economic shutdowns and a surge in unemployment claims.[439] In April 2020, the unemployment rate reached 15 percent—the highest unemployment rate since data collection began in 1948.[440] Within just a few months, unemployment benefit claims soared to more than 58 million as businesses closed and workers lost their jobs, with more than 7 million UI applications filed in a 23-week span.[441]

The DOL establishes federal guidelines that require each state to manage and fund its own unemployment benefits program with the federal government allowing extensions and expansions of benefits during emergencies, including public heath crises.[442] In response to massive unemployment, Congress enacted several pandemic relief packages to provide financial support to employers, employees, and the newly unemployed:

- FFCRA: The first relief program that required certain employers to provide emergency paid sick leave and expanded family and medical leave for individuals with reasons related to COVID-19.[443]

- CARES Act: The largest relief package that created three new temporary federal unemployment benefit programs. These fully federally funded programs expanded existing UI benefits, created additional weeks of temporary benefits, and increased UI benefits to groups that were traditionally not eligible to apply:[444]

    - FPUC: Established weekly $600 payments in addition to regular UI and extended benefits.[445]

    - PEUC: Extended the length of time individuals could receive UI benefits, allowing the claimant to claim benefits for up to 79 weeks.[446]

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[439] 31 CFR Part 35.
[440] Fraud in Federal Unemployment Insurance Programs: Hearing Before Committee on Ways & Means, 118th Cong. 1, (Feb. 8, 2023) (Statement of Michael E. Horowitz, Chair, Pandemic Response Accountability Comm., Inspector General, DOJ).
[441] Nigel Chiwaya & Jiachuan Wu, *The coronavirus has destroyed the job market in every state*, NBC NEWS (Apr. 14, 2020).
[442] Fraud in Federal Unemployment Insurance Programs: Hearing Before Committee on Ways & Means, 118th Cong. 1, (Feb. 8, 2023) (Statement of Michael E. Horowitz, Chair, Pandemic Response Accountability Comm., Inspector General, DOJ).
[443] Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 177 (2020).
[444] CARES Act, *supra* note 396.
[445] *Id.*
[446] *Id.*

- PUA: Expanded eligibility of UI to self-employed workers, freelancers, independent contractors, and part-time workers impacted by COVID-19, providing up to 79 weeks of unemployment benefits.[447]

In total, an estimated $872 billion was allocated to COVID-19 UI benefit programs.[448] These programs were implemented rapidly as Congress, governors, and state legislatures pushed for state workforce agencies to distribute funds efficiently. However, the unprecedented volume of claims placed enormous strain on states' unemployment systems contributing to delays, confusion, improper payments, and fraud.[449] The DOL ETA was tasked with overseeing traditional UI benefit claims, ensuring states distributed effectively while maintaining accountability.[450] ETA officials reported that the COVID-19 pandemic led to a tenfold increase in pandemic-related UI claims for federal and state programs, overwhelming the capacity of state systems.[451]

The Consolidated Appropriations Act of 2021implemented refined integrity measures which required documentation for claimants filing benefits after January 31, 2021. States had to verify PUA applicants and include a statutory requirement for weekly self-certification. States were required to have a process which addressed work refusals including a method for employers to properly report these refusals. [452]

ARPA extended pandemic UI benefits for an additional six months, including continued weekly FPUC payments and a 29-week extension of PEUC benefits.[453] By March 2021, nearly all businesses had reopened, and a mass vaccination program was well under way with one-third of Americans having already reported to at least one dose of the vaccine.[454] Extending these programs, with insufficient oversight, allowed fraudsters, international criminals, and foreign adversaries to steal billions in taxpayer dollars through UI fraud.[455]

FINDING: Fraudulent Unemployment Insurance Payments Total More Than $191 Billion.

At the onset of the COVID-19 pandemic, unemployment claims skyrocketed to unprecedented levels. GAO estimated that 11 to 15 percent of UI claims were fraudulent,

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[447] *Id.*
[448] MITRE, *Best Practices and Lessons Learned From the Administration of Pandemic Related Unemployment Benefits Program* (Feb. 2022).
[449] Where Do We Go From Here? Examining a Path Forward to Assess Agencies' Efforts to Prevent Improper Payments and Fraud: Hearing Before Subcomm. on Gov't Operations and the Federal Workforce, H. Comm. on Oversight and Accountability, 118th Cong, 2 (Sept. 10, 2024).
[450] *OIG Oversight of the Unemployment Insurance Program,* U.S. DEP'T OF LABOR (last updated Dec. 15, 2023) *available at* https://www.oig.dol.gov/doloiguioversightwork.htm [hereinafter "OIG Oversight of the Unemployment Insurance Program"].
[451] U.S. DEP'T OF LABOR, 19-24-002-03-315, A REVIEW OF PANDEMIC UNEMPLOYMENT INSURANCE RELIEF AND ITS IMPACT ON SIX DIFFERENT U.S. COMMUNITIES (Mar. 28, 2024).
[452] Consolidated Appropriates Act, Pub. L. No. 117-328, 136 Stat. 4459 (2022).
[453] Julie M. Whittaker & Katelin P. Isaacs, CONG. RESEARCH SERV., R46687, *Current Status of Unemployment Insurance (UI) Benefits: Permanent-Law Programs and COVID-19 Pandemic Response* (last updated Aug. 22, 2021).
[454] Liz Hamel, *et al., KFF COVID-19 Vaccine Monitor: March 2021*, KFF (Mar. 30, 2021).
[455] U.S. Dep't of Labor, *supra* note 450.

resulting in between $100 billion and $135 billion of improper payments potentially linked to fraud.[456] After further investigation by DOL IG, it found that at least $191 billion was wrongfully paid out to bad actors who exploited individuals' PII.[457]

In December 2021, ETA reported an improper payment rate of 18.71 percent for two of the three pandemic UI programs—PEUC and EPUC—excluding monetary losses from the PUA program.[458] A year later, ETA reported the percentage of improper payments rose almost three precent for the same two programs.[459] As of September 13, 2023, DOJ announced more than 700 enforcement actions, including criminal charges, against 371 defendants for more than $836 million in alleged UI fraud.[460] Most of these losses could have been prevented if Congress and Federal agencies provided up-to-date technologies along with proper verification methods for oversight, something GAO has been specifically recommending for more than ten years.[461]

Agencies are actively working to recover funds lost to fraudsters but are having difficulties tracking down some of the money, as some was converted into tangible assets.[462] Fraudsters bought cars, property, and even hired hitmen with the money stolen from taxpayers.[463] The figure below shows the total estimated fraudulent and nonfraudulent overpayments that occurred between March 2020 and March 2023 versus how many fraudulent or erroneous payments have been recovered during this time period.[464]

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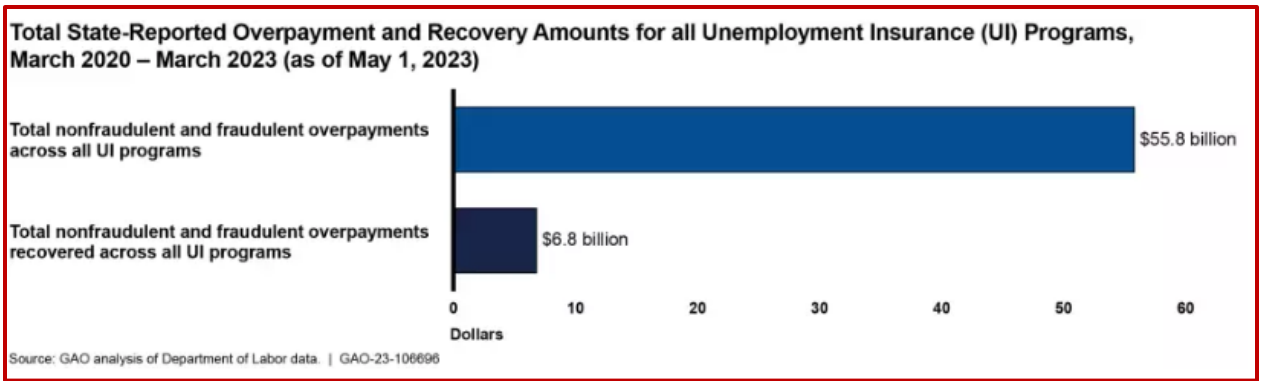
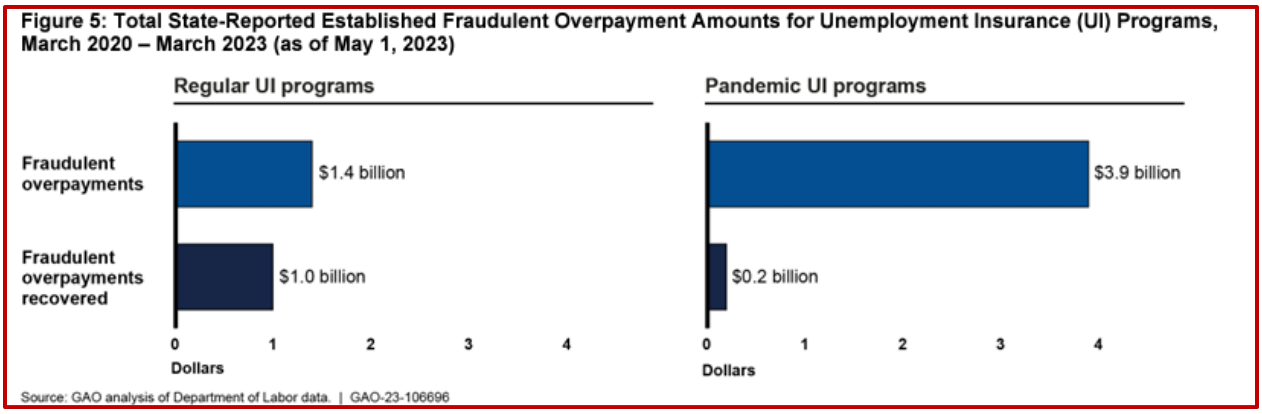
[456] GAO, GAO-23-106696, UNEMPLOYMENT INSURANCE: ESTIMATED AMOUNT OF FRAUD DURING PANDEMIC LIKELY BETWEEN $100 BILLION AND $135 BILLION (Sept. 12, 2023).
[457] U.S. Dep't of Labor, *supra* note 455.
[458] Matt Weidinger, *Official Estimate of Unemployment Misspending Rises to $191 billion—and That Is Still the "Low End"*, AEI (Feb. 9, 2023).
[459] GAO UNEMPLOYMENT INSURANCE, *supra* note 456.
[460] *Id.*
[461] *Id.*
[462] *Id.*
[463] *COVID money to hire hitmen?,* OLEAN TIMES HERALD (Nov. 11, 2023).
[464] GAO UNEMPLOYMENT INSURANCE*, supra* note 456.


Total State-Reported Overpayment and Recovery Amounts for all Unemployment Insurance (UI) Programs, March 2020 – March 2023 (as of May 1, 2023)
Total nonfraudulent and fraudulent overpayments across all UI programs
$55.8 billion
Total nonfraudulent and fraudulent overpayments recovered across all UI programs
$6.8 billion
0
10
20
30
40
50
60
Dollars
Source: GAO analysis of Department of Labor data. | GAO-23-106696

States have continuously reported fraudulent UI overpayments in both traditional and pandemic UI programs. The data from March 2020 and March 2023 compares the stark differences in how much money was lost during the pandemic compared to traditional UI programs.[465] States have only identified $1.2 billion in payment recoveries out of $5.3 billion lost across FPUC, PEUC, and UI programs.[466] The figure below shows the amount of money lost to fraudulent overpayments and subsequent recoveries by states for both the traditional and pandemic UI programs.[467] The prior lapses in the traditional UI benefit claim system opened the door for fraud, waste, and abuse of pandemic-era UI benefits.



Organized Crime Networks, Domestic Fraudsters, Identity Thieves, and Prison Imamates Exploited Stolen Identities to Fraudulently File for Pandemic UI Benefits

Fraudsters exploited the federal government's pandemic relief programs by using the SSNs of deceased people and federal prisoners to receive unemployment benefits during the pandemic.[468] The U.S. Attorney Office for the Western Division of Virginia charged a woman with leading a conspiracy to commit pandemic-related UI fraud in connection with a scheme

[465] GAO UNEMPLOYMENT INSURANCE, *supra* note 456.
[466] *Id.*
[467] *Id*.
[468] Richard Lardner*, et al., The Great Grift: How billions in COVID-19 relief aid was stolen or* wasted, AP NEWS (June 12, 2023).

involving the filing of fraudulent claims.[469] This defendant conspired with more than 35 individuals to file fraudulent claims of UI benefits. The co-conspirators included 15 prison inmates, totaling fraudulent claims for at least 37 individuals resulting in $499,000 lost.[470]

In another case, Homeland Security Investigations Baltimore, alongside other federal agencies, investigated a Maryland man who plead guilty to fraudulently obtaining at least $1.3 million in COVID-19 UI benefits.[471] The defendant conspired with others to impersonate victims by submitting fraudulent claims for UI benefits in Maryland, Georgia, Illinois, Tennessee, Virginia, and Washington, D.C. The criminal group obtained PII, without the victims' knowledge or consent, and shared them between themselves and others to facilitate the fraud. They applied for at least $1.3 million in UI benefits using the names and information of more than 183 victims.[472]

The Structure of the PUA Program Enabled Widespread Fraud at an Unprecedented Level

In August 2023, DOL reported an improper payment rate of 35.9 percent for the PUA program.[473] During the first nine months of the program, claimants were not required to provide any documentation or evidence of earnings, despite states certifying individuals' eligibility for benefits.[474] State workforce agencies, responsible for distributing funds to claimants, lacked the necessary information to verify the credibility of the claims.[475] These agencies were unable to confirm prior employment or self-employment, nor verify wage amounts beyond what was self-reported by claimants.[476] Additionally, states failed to cross-check claims against critical databases to ensure applicants were not filing in multiple states, incarcerated, or flagged as high-risk for fraud. Since the PUA provided UI benefits to a new population of workers, states struggled with identity verification because claimants were outside of the federal-state taxation system.[477] This absence of robust verification measures allowed criminals to exploit the system by receiving multiple payment cards, with some sent to the same address, and by fraudulently obtaining benefits in the names of incarcerated individuals.

Many of these vulnerabilities stemmed from delays in implementing proper cross-matching of applicant data with available databases during the early stages of the program. As a result, some legitimate claimants later discovered they had been victimized by fraud when they received IRS1099-G forms for unemployment benefits that were paid out in their name.[478]

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[469] Press Release, U.S. Att'ys Office, Western Distr. of Virg., Russell Co. Woman Pleads Guilty to $499,000 Unemployment Fraud Scheme (Mar. 18, 2021).
[470] *Id.*
[471] *Id.*
[472] News Release, U.S. Immigrations and Customs Enforcement, Maryland man admits to $1.3 million COVID-19 relief fraud scheme (Feb. 9, 2023).
[473] U.S. Dep't of Labor, *supra* note 455.
[474] *Id.*
[475] GAO, GAO-23-106696, UNEMPLOYMENT INSURANCE: ESTIMATED AMOUNT OF FRAUD DURING PANDEMIC LIKELY BETWEEN $100 BILLION AND $135 BILLION (Sept. 12, 2023).
[476] *Id.*
[477] Katelin P. Isaacs & Julie M. Whittaker, CONG. RESEARCH SERV., R47079, *Unemployment Insurance: Program Integrity and Fraud Concerns Related to the COVID-19 Pandemic Response* (Apr. 24, 2022).
[478] *Id.*

FINDING:	States Failed to Improve Their Preparedness and Implement Data-Driven Oversight, Leading to Increased Fraud Across All Pandemic-Related Unemployment Insurance Programs.

The DOL IG identified significant weaknesses in states' abilities to measure, report, and reduce improper payments in the traditional UI program.[479] For more than 20 years, DOL IG consistently reported that the UI program has some of the highest improper payments in the federal government.[480] In 15 of the past 19 years, improper payments in the regular UI program exceeded ten percent.[481] States are required to issue weekly benefit payments while ensuring claimants eligibility, but improper payments persisted. Common causes include claimants failing to meet job search requirements, continuing to claim benefits after returning to work, or misreporting earnings.[482] Additionally, employers often fail to provide timely information about employee separations, which further contributes to improper payments.[483]

Fraud significantly contributed to improper payments within pandemic UI programs. Despite prior recommendations for systematic improvements, the improper payment rate in pandemic UI programs surged to 21.52 percent in 2022, resulting in an estimated $191 billion in improperly distributed UI benefits.[484] These outcomes underscore several deficiencies in states' preparedness and highlight long-standing systematic issues withing state UI systems.

Several states encountered considerable challenges in mitigating unemployment insurance fraud, demonstrating a lack of coordination and missed opportunities for accountability.[485] Although the federal government moved quickly to provide emergency funds for those in need, the system's vulnerabilities allowed ineligible individuals and fraudsters to take advantage of the program.[486]

The DOL established deadlines for states to report on their UI program performance, but certain states failed to comply. This non-compliance coupled with inaccurate reporting, hampered the federal government's ability to ensure proper oversight and accountability. Frequently, flagged transactions that had "suspicious email accounts" were not all fraudulent transactions and not all fraudulent transactions may be flagged.[487] This systematic failure requires a more thorough investigation with more staff.[488]

States such as California, New York, and Pennsylvania demonstrated a lack of urgency in distributing benefits and repeatedly missed reporting deadlines related to performance of their UI

[479] U.S. Dep't of Labor, *supra* note 455.
[480] *Id.*
[481] *Id.*
[482] *Id.*
[483] *Id.*
[484] PRAC, *supra* note 419.
[485] Hearing on The Greatest Theft of Taxpayer Dollars: Unchecked Unemployment Fraud: Hearing Before H. Comm. On Ways & Means, 118th Cong. 1, (Feb. 8, 2023) (Statement of Gene L. Dodaro, Comptroller General of the U.S.).
[486] *Id.*
[487] *Id.*
[488] *Id.*

programs. California's Employment Development Department [hereinafter "EDD"] struggled with an overwhelming backlog of claims. The EDD consistently missed critical deadlines and submitted incomplete reports.[489] In one instance, California submitted its required reports for the FPUC and PEUC programs just before the deadline but filed them with zeros—falsely indicating no activity.[490] This reporting was clearly inaccurate given the state's immense population, and such failures impeded oversight efforts and exposed taxpayer funds to greater risk of fraud.[491]

Pennsylvania also faced significant challenges, as it was unprepared for the surge in fraudulent claims, many of which originated from outside the U.S.[492] The state failed to implement modern digital identification services to manage the spike in claims during the pandemic.[493] New York similarly neglected to use databases or systems to cross-reference claims for potential fraud. As a result, checks were sent to the same address multiple times, issued to individuals incarcerated, in prison, and sent to the claimants using fraudulently obtained social security numbers and government identification.[494]

[489] Auditor of the State of California, Report Number: 2020-128/628.1, *EDD's Poor Planning and Ineffective Management Left It Unprepared to Assist Californians Unemployed by COVID-19 Shutdowns* (Jan. 26, 2021).
[490] *Id.*
[491] PRAC*, supra* note 419.
[492] *Id.*
[493] *Id.*
[494] *Id.*

III. Economic Injury Disaster Loan Program

The SBA Disaster Assistance Program is the federal government's primary program for providing disaster relief to businesses.[495] In response to the COVID-19 pandemic, CVPR deemed COVID-19 a disaster which authorized SBA to provide EIDLs to businesses and nonprofits affected by the COVID-19 pandemic.[496] EIDLs are low-interest, fixed-rate, long-term COVID- loans to provide covered businesses with working capital to meet ordinary and necessary operating expenses.[497]

In addition to CVPR, the CARES Act expanded EIDL by providing $10 billion more to provide emergency loans.[498] The money allocated to SBA for the COVID-19 pandemic was a significant increase compared to other natural disasters including Hurricanes Sandy, Irma and Maria.[499] EIDL loans are long-term loans with a 30-year term and a 3.75 percent fixed interest rate for business and 2.75 percent fixed interest rate for non-profit organizations.[500] Through third-party lending firms, SBA disbursed over $400 billion in COVID-19 EIDL funds. [501]

The SBA IG and other oversight bodies found the COVID-19 EIDL program had repayment failures and an abundance of fraudulent payments.[502] The SBA IG stated this was nothing short of surprising based on SBA's disaster loan program suffering increased vulnerability to fraud and unnecessary losses when loan transactions are expedited to provide quick relief.[503]

FINDING:	The U.S. Small Business Administration Disaster Programs, Including COVID-19 Economic Injury Disaster Loans, Suffered Increased Vulnerability to Fraud and Unnecessary Losses of at Least $200 Billion.

At least 17 percent of all COVID-19 EIDL and PPP funds were disbursed to potentially fraudulent actors. This amounted to approximately $200 billion in fraudulent payments out of the $1.2 trillion SBA disbursed through EIDL and PPP programs. Like other COVID-19 relief programs, fraudsters falsified documents, used personally identifiable information, inflated business revenues, submitted multiple applications, and misused loan funds.[504] Oftentimes, individuals who defrauded the EIDL program also defrauded PPP using the same methods for each of the programs.

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[495] Press Release, U.S. Small Businesses Admin., SBA Tops $200 Million in Disaster Assistance Loans for Hurricane Beryl (Aug. 28, 2024).
[496] *Id.*
[497] OFFICE OF INSPECTOR GENERAL U.S. SMALL BUSINESS ADMIN., REPORT 23-09, WHITE PAPER: COVID-19 PANDEMIC EIDL AND PPP LOAN FRAUD LANDSCAPE (June 27, 2023).
[498] CARES ACT, *supra* note 396.
[499] *Id.*
[500] Bruce R. Lindsay*, et al*., CONG. RESEARCH SERVS., R47509, SBA COVID-19 EIDL Financial Relief: Policy Options and Considerations (Apr. 18, 2023).
[501] U.S. Dep't of Labor, *supra* note 479.
[502] *Id.*
[503] *Id.*
[504] *Id.*

Fraudsters Used False Employee Identification Numbers to Apply for EIDL Loans That Were Not Vetted by the SBA

Sole proprietors and independent contractors applying for the EIDL program were not required to provide EINs. At that time, SBA limited applicants to receive $1,000 per employee, with a legislated cap on EIDL advance amount of $10,000 per employee.[505] These EIDL advances were structured as grants, which did not require repayment.[506] Applicants self-certified the number of employees they had, and SBA did not verify this information.[507]

This lack of verification created an opportunity for fraudulent activity. Some individuals fraudulently applied for and obtained grants exceeding $1,000 by falsely claiming to have multiple employees despite not possessing an EIN.[508] The SBA IG conducted analysis of all COVID-19 EIDL advances to identify applications from sole proprietors or independent contractors who claimed more than one employee with the required EIN.[509]

One example of EIDL fraud was two brothers who used fictitious aliases, stolen identities, defunct corporate entities, and new business entities with no actual business operations.[510] They claimed to be sole proprietors or independent contractors who claimed more than one employee while not possessing the required EIN and tried to obtain more than $1 million dollars in COVID-19 relief loans including EIDL.[511]

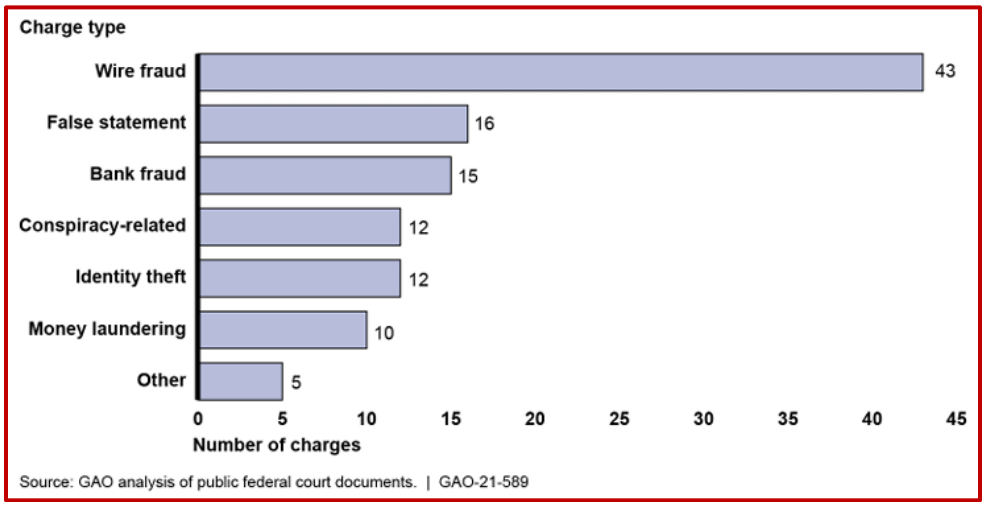
EIDL Advances Aided Millions of Illegitimate Entrepreneurs During the Early Stages of the Pandemic

In another SBA IG investigation, SBA provided the IG with a list of EIDL advances and grants suspected or confirmed to be linked to fraudulent activity.[512] Two individuals were convicted for orchestrating an elaborate telemarketing scheme in which they submitted more than 400 fraudulent COVID-19 EIDL applications, securing more than $1.5 million in EIDL advances for ineligible applicants.[513] In exchange for a fee, the defendants obtained PII from victims to submit fraudulent COVID-19 EIDL applications to SBA.[514] This case was initiated based on information provided by a financial institution in response to a joint fraud alert issued by the SBA IG and USSS.[515]

The scope of fraud related to EIDL loans resulted in significant financial losses. In March 2021, GAO conducted an analysis of DOJ fraud cases. The analysis highlighted a substantial

[505] *Id.*
[506] *Id.*
[507] *Id.*
[508] *Id.*
[509] *Id.*
[510] *Id.*
[511] *Id.*
[512] *Id.*
[513] *Id.*
[514] *Id.*
[515] *Id.*

increase in EIDL-related fraud, particularly wire fraud, which was the most prevalent type of fraud in 2021 and continued to rise through 2021.[516]



FINDING: U.S. Small Business Administration Did Not Implement Proper Oversight Controls to Prevent Fraudulent Economic Injury Disaster Loans.

The GAO, SBA IG, and SBA's financial auditors identified significant weaknesses in SBA's internal controls, which allowed potentially ineligible or fraudulent entities to receive EIDL relief payments.[517] Despite these findings, SBA has not fully implemented many of the recommendations provided by GAO and OIG.[518] For instance, in January 2021, GAO advised SBA implement data analytics to detect fraudulent applications. However, SBA did not immediately act to refine its fraud detection measures nor adopted the recommended data analytics program.[519]

In March 2021, GAO further reported that SBA lacked a comprehensive plan to assess and mitigate fraud risks within the EIDL program.[520] While SBA agreed to address these concerns, it did not immediately take the necessary steps to fully implement the GAO's recommended fraud risk assessment and oversight strategy.[521]

In an October 2020 report, SBA IG highlighted deficiencies such as inadequate responses to fraud alerts and the issuance of duplicate loans.[522] The IG issued ten recommendations, including the review of suspicious loans and the strengthening of verification controls.[523] While

[516] *Id.*
[517] GAO COVID RELIEF FRAUD SCHEMES, *supra* note 409.
[518] *Id.*
[519] *Id.*
[520] *Id.*
[521] *Id.*
[522] *Id.*
[523] *Id.*

SBA partially agreed with these recommendations and took some corrective actions, many of the concerns raised by both OIG and GAO were not immediately resolved.[524]

In December 2020, SBA's independent financial auditor identified two material weaknesses in SBA's internal controls: (1) approval of EIDL loans and advances and (2) oversight of the contractor managing the EIDL application system.[525] These weaknesses were linked to issues like duplicate payments and loans provided to ineligible borrowers. The audit revealed that SBA failed to implement proper controls to monitor the contractor's processes, such as checks for duplicate applications, bank account verification, and identity validation.[526]

The auditors largely attributed these deficiencies to SBA's prioritization of the rapid implementation of CARES Act provisions over the establishment of effective internal controls.[527] Seven recommendations were made to address these shortcomings, including a review of the EIDL portfolio for ineligible transactions, improving loan approval controls, staff training, and enhanced contractor oversight.[528]

Additionally, the audit identified a material weakness in SBA's entity-level controls, indicating that SBA management did not design or implement adequate controls to support the expanded programs under the CARES Act.[529] The audit issued five recommendations to improve these controls, including holding individuals accountable for internal control oversight and ensuring proper documentation of processes.[530]

While SBA disagreed with some of the material weaknesses and did not take a clear stance on the recommendations, by May 2021, SBA began working with a contractor to address oversight issues and assess the adequacy of controls in processing EIDL loans and advances, but millions of dollars were already lost to ineligible claimants.[531]

[524] *Id.*
[525] *Id.*
[526] *Id.*
[527] *Id.*
[528] *Id.*
[529] *Id.*
[530] *Id.*
[531] *Id.*

IV. Transnational Fraud

The unprecedented amount of emergency relief distributed throughout the COVID-19 pandemic created a target for transnational criminal organizations. Despite prior congressional initiatives aimed at addressing waste, fraud, and abuse, federal agencies have not sufficiently implemented fraud prevention measures to deter, detect, and defeat international organized crime syndicates.[532]

Transitional criminal networks engaged in large-scale operations that submitted fraudulent claims, laundered illicit funds through financial systems, and transferred proceeds across borders.[533] It is estimated that at least half of the federal funds lost through the PPP and UI relief programs were stolen by international fraudsters.[534] This exploitation of pandemic relief programs has not only undermined domestic recovery efforts but has also fortified organized crime syndicates, underscoring the urgent need for enhanced global cooperation and enforcement to safeguard public funds.

Oversight of Transnational Crime

Many federal government agencies played a central role in the oversight of relief fund fraud committed by transnational organizations. The DOJ, FBI, DHS, SBA, IRS, and USSS all had separate investigations into foreign criminal activity related to relief funds.[535]

Methods of Exploitation

International criminal organizations mirrored the tactics of domestic fraudsters, utilizing similar methods to obtain sensitive information from vulnerable Americans.[536] Many fraudulent relief claims were filed using illegally acquired personal data—including PII, much of which stemmed from pre-existing data breaches.[537] Cybercriminals also employed phishing attacks to further exploit individuals' information, targeting the most vulnerable populations.[538]

Among the various COVID-19 relief programs, UI fraud emerged as one of the most prevalent areas of exploitation.[539] The rapid need for an expedited distribution of funds led to the removal of several verification requirements, creating a prime target for transnational criminals. These fraudsters successfully impersonated jobless Americans by leveraging stolen identity information available for purchase in the dark web.[540] This comprised data often included critical personal details such as birthdates, SSNs, and addresses.

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[532] *Id.*
[533] *Id.*
[534] *Id.*
[535] Ken Dilanian & Laura Stickler, *'Biggest fraud in a generation': The looting of the Covid relief plan known as PPP,* NBC NEWS (Mar. 28, 2022).
[536] COUNCIL OF THE INSPECTORS GENERAL ON INTEGRITY AND EFFICIENCY, COVID-19 FRAUD ENFORCEMENT TASK FORCE 2024 REPORT (Apr. 2024).
[537] *Id.*
[538] *Id.*
[539] *Id.*
[540] *Id.*

FINDING:	Lackluster Oversight Resulted in Transnational Criminal Organizations and Fraudsters Stealing U.S. Taxpayer Money from Pandemic Relief Funds.

International criminal organizations and foreign government-affiliated actors exploited the urgency of relief programs and orchestrated sophisticated fraud schemes that span multiple countries.[541]

Some notable cases are:

1. Chinese government-linked hackers stole at least $20 million in U.S. Government COVID-19 relief funds.[542]

An USSS investigation revealed that hackers affiliated with the Chinese government, specifically identified as APT41, were implicated in theft of $20 million of U.S. Government COVID-19 relief funds.[543] APT 41 has been linked to fraudulent activity in the past, specifically traditional unemployment insurance fraud against SBA across dozens of states.[544] APT41 also has a history of espionage activities on behalf of the Chinese government, including attacks on pro-democracy politicians in Hong Kong and data breaches affecting more than 100 organizations.[545] Investigations of foreign pandemic-related fraud also seem to point back to foreign state-affiliated hackers, such as this one.

2. A Nigerian fraud ring stole $10 million in pandemic relief funds.[546]

Mr. Abemdemi Rufai, a Nigerian government official, organized a large-scale cyberfraud scheme—named Scattered Canary—targeting COVID-19 relief funds. Scattered Canary, a business email compromise operation, filed at least 174 fraudulent unemployment claims in Washington state and 17 in Massachusetts that were all accepted, all with an expected payout of $5.4 million.[547]

3. An Indian national stole $8 million in a COVID-19 relief fraud scheme.[548]

A federal grand jury in Newark, New Jersey indicted an Indian national for submitting fraudulent PPP loan applications totaling more than $8.2 million.[549] The defendant submitted at least 17 applications on behalf non-existent companies, using false information about employees

[541] *Id.*
[542] Sarah Fitzpatrick & Kit Ramgopal, *Hackers linked to Chinese government stole millions in Covid benefits, Secret Service says*, NBC NEWS (Dec. 5, 2022).
[543] *Id.*
[544] *Id.*
[545] *Id.*
[546] Press Release, U.S. Att'ys Office Dist. of Mass., Nigerian Man Arrested in Alleged $10 Million Pandemic Unemployment Assistance Fraud Scheme (Aug. 19, 2024).
[547] *Id.*
[548] Press Release, DOJ, Indian National Charged in $8 Million COVID-19 Relief Fraud Scheme (Nov. 9, 2022).
[549] *Id.*

and payroll.[550] He also fabricated tax filings on behalf of a non-existent business to receive more relief payments. He reportedly received $3.3 million in loan proceeds which he then laundered. The defendant faces multiple charges including wire fraud, money laundering, and aggravated identity theft.[551]

FINDING:	Domestic and International Fraudsters that Stole from Pandemic Relief Programs were also Connected to Other Organized Crimes.

Fraudsters involved with stealing millions of dollars were also involved in other federal crimes including wire fraud and drug smuggling. In a DOL IG investigation, a defendant was sentenced to 92 months of federal incarceration for his role in a scheme involving the possession of 15 or more access devices and a possession of a firearm by a convicted felon.[552] DOL IG has continued to connect abuse of UI relief funds to organized criminal groups. The National UI Fraud Task Force was created to combat fraud of UI perpetrated by domestic and international criminal organizations.[553] Many of these include street-level criminal organizations with ties to illegal guns and drugs.[554]

The U.S. Attorney's Office charged six individuals, including two Maryland State Department of Labor subcontractors with participating in a conspiracy to fraudulently obtain $3.5 million in UI benefits.[555] The lead defendant now faces separate narcotics and firearms charges, including allegations that he unlawfully possessed a machine gun in furtherance of a drug trafficking crime.[556] Another convicted felon charged with CARES Act fraud also committed firearm offenses and possession with the intent to distribute fentanyl.[557]

The U.S. Attorney's Office for the District of Maryland targeted cases with connections between COVID-19 fraud and individuals involved with violent crime, organized criminal networks, business email compromise schemes, and narcotics distribution.[558] Using probable cause from the commission of COVD-19 fraud, agents conducted searches and seized illegal firearms, narcotics, and stolen PII. Many cases of COVID-19 fraud have led agents to defendants with ghost guns, machines guns, and illicit drugs.

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[550] *Id.*
[551] *Id.*
[552] Waste, Fraud, and Abuse Go Viral: Inspectors General on Curing the Disease: Hearing Before Subcomm. on Gov't Operations and the Fed. Workforce H. Comm. on Oversight and Accountability, 118th Cong, 1. (Mar. 9, 2023) (Testimony of Larry D. Turner, Inspector General, Office of Inspector General U.S. Dep't of Labor).
[553] *Id.*
[554] *Id.*
[555] Press Release, U.S. Attorney's Office District of Maryland, Six Individuals, Including Two Maryland State Department of Labor Subcontractors, Facing Federal Indictment for a Scheme to Fraudulently Obtain COVID-19 CARES Act Unemployment Insurance Benefits (Dec. 15, 2023).
[556] *Id.*
[557] *Id.*
[558] *Id.*

V. Flaws in Pandemic Program Oversight

The COVID-19 pandemic highlighted critical weaknesses in oversight measures to prevent waste, fraud, and abuse in federally funded emergency relief programs. While these relief programs were aimed at providing critical assistance, the urgency of combating a public health crisis exposes significant weaknesses in oversight. The PRAC was included in the CARES Act to support and coordinate independent oversight of pandemic relief spending.[559] The PRAC facilitated coordination across IGs to ensure wrongdoers are held accountable for misusing taxpayer dollars.[560] Since April 2020, PRAC has worked with state and federal oversight agencies to oversee more than $5 trillion in federal pandemic relief emergency spending.[561]

Federal agencies, such as the SBA, USSS, Treasury, DOL, GAO, and HHS, are some of the 20 agencies that led pandemic relief oversight efforts to bring money back to the taxpayer.[562] These agencies with their respective IGs were responsible for detecting and preventing fraud, waste, and abuse in pandemic relief efforts, though many of them faced challenged in carrying out this oversight effectively.[563]

During the 118th Congress, the House Committee on Oversight and Accountability held hearings to expose the massive fraud in pandemic relief programs and how federal agencies were simply unprepared for the influx of domestic and international fraud.[564] Federal agencies failed to utilize tools to prevent fraud from occurring in the first place, resulting in billions of dollars lost due to improper payments. Simple measures and up-to-date technology could have prevented millions of dollars being lost within days of rollout. According to testimony, the Treasury do-not-pay list was not included within the internal control environment, allowing billions of dollars in likely improper payments.[565]

Federal and state agencies had significant lapses in coordination, insufficient resources for oversight, weak data sharing and reporting mechanisms, and delays in enforcement and accountability for pandemic relief programs.[566] Federal and state agencies must be held accountable for the billions of dollars lost due to their flaws in oversight.

FINDING:	Federal Agencies Overseeing Pandemic Relief Funds were Needlessly "Siloed Off" from Each Other, Which Prevented Wholistic Tracking and Disbursing of Funds to Prevent Fraud.

[559] *Fact Sheet – Two-Year Mark of the CARES Act and the Creation of the Pandemic Response Accountability Committee*, PANDEMIC OVERSIGHT, *available at* https://www.pandemicoversight.gov/media/file/prac-two-year-fact-sheet.
[560] *Id.*
[561] *Id.*
[562] Federal Pandemic Spending: A Prescription for Waste, Fraud and Abuse: Hearing Before H. Comm. on Oversight and Accountability, 118th Cong. 1, (Feb. 1, 2023).
[563] *Id.*
[564] Press Release, H. Comm. on Oversight and Accountability, Subcomm. on Gov't Operations and the Federal Workforce, Hearing Wrap Up: Existing Flaws, Structural Weaknesses, and Unprecedented Levels of Spending Led to Rampant Fraud in Pandemic Relief Programs (Mar. 10, 2023).
[565] *Id.*
[566] *Id.*

Many domestic and foreign fraudsters used the SSNs of deceased individuals and federal prisoners to get unemployment checks.[567] These fraudsters were able to collect these checks in multiple states because federal loan applications were not cross-checked against a Treasury database that would have raised red flags about sketchy borrowers.[568]

Pursuant to the Payment Integrity Information Act, federal agencies are required to develop and implement internal controls that prevent and detect fraud and other improper payments.[569] One requirement is agencies must verify the identities and eligibility of individuals and organizations seeking pandemic funding prior to issuing payments, specifically by accessing the DNP list.[570] Although, at the beginning of the pandemic, agencies did not have access to the full DNP list because SSA was not legally able to share the full DNP list.

The DNP Was Not 100 Percent Accurate and Lacked Sufficient Information to Cross-Check

The DNP list includes individuals who are deceased and excluded from doing business with the government.[571] According to Treasury's website, the DNP list exists to prevent improper payments from federal programs but does not have access the SSA's full DMF.[572] Instead, it currently receives a limited version of the DMF, provided by the National Technical Information Service, along with state provided death related data.[573] The full DMF contains death information SSA collects, including state-owned data, which is cross-referenced with SSA's records on individuals with SSNs.[574]

This lack of access prevented PRAC from conducting a full investigation into fraudulent loan applications, leaving 5,097 fraudulent loan applications unable to be accounted for because of the lack of information sharing between the SSA and Treasury.[575] The SBA IG office identified the DNP system as a critical control that could have been implemented at the onset of these relief programs to prevent billions of dollars from being improperly disbursed.

The Social Security Act currently does not allow full death data sharing between the SSA and Treasury.[576] The Consolidated Appropriations Act of 2021 allowed the SSA to share, to the extent feasible, its full death data with DNP list only for a 3-year period.[577] When combating domestic and transnational fraud, this does not allow enough time for agencies to conduct full oversight and recover improperly paid funds.

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[567] *Id.*
[568] *Id.*
[569] *Id.*
[570] *Id.*
[571] *Id.*
[572] *Id.*
[573] *Id.*
[574] *Id.*
[575] PANDEMIC RESPONSE ACCOUNTABILITY COMMITTEE, PRAC-2023-02, FRAUD ALERT FOLLOW-UP: IMPROVED SHARING OF DEATH RECORDS AND USE OF THE DO NOT PAY SYSTEM WOULD STRENGTHEN PROGRAM INTEGRITY AND BETTER PROTECT THE PUBLIC (May 11, 2023).
[576] Federal Pandemic Spending, *supra* note 562.
[577] *Id.*

FINDING: Federal Agencies Did Not Require and Failed to Validate Information Provided by Applicants to Properly Verify Eligibility.

The Payment Integrity Information Act mandated agencies use effective pre-payment controls like the DNP list to prevent improper payments.[578] However, during the pandemic, many agencies allowed applicants to self-certify their eligibility for programs, which led to significant fraud and improper payments.[579]

For instance, under the Emergency Rental Assistance program, Treasury awarded funds without verifying applicants' rental agreements or financial need. Similarity SBA allowed self-certification for both PPP and EIDL loans. This lack of verification contributed to an estimated $200 billion in fraud between both programs.[580] The SBA failed to implement front-end controls when verifying applicants. SBA OIG identified that the Treasury Offset Program Debt Database, which contains information regarding individuals who are delinquent on child support obligations, was not implemented to cross-check any claimants applying for PPP or EIDL loans.[581] The SBA also did not manually check the DNP list prior to approving a loan or grant. The SBA IG identified more than $120 million in loans and $24 million in grants to borrowers listed on the DNP list.

DNP Database	Number of Loans	Total Loans ($)	Number of Grants	Total Grants ($)	Total Loans and Grants ($)
Treasury Offset Program Debt Check (delinquent child support only)	1,452	$100,658,291	1,851	$22,268,000	$122,926,291
System for Award Management Exclusion Records	88	10,182,400	94	984,000	11,166,400
Death Master File – Public	5	904,800	10	85,000	989,800
American Infosource-Obituary	66	8,650,700	63	505,000	9,155,700
American Infosource-Probate	3	941,600	9	66,000	1,007,600
Department of State – Public	0	0	2	20,000	20,000
Total	1,614	$121,337,791	2,029	$23,928,000	$145,265,791

Source: SBA OIG analysis

The Department of Labor Allowed for Self-Certification of the Unemployment Insurance PUA programs, Straining the States

The expanded coverage in the CARES Act for the PUA program posed significant challenges to states as they implemented processes to determine initial and continued program

[578] *Id.*
[579] *Id.*
[580] Garrett Hatch & Natalie R. Ortiz, Cong. Research Servs., R47902, Improper Payments in Pandemic Assistance Programs (Jan. 19, 2024).
[581] U.S. SMALL BUSINESS ADMIN. OFFICE OF INSPECTOR GENERAL, REPORT 24-18, EVALUATION OF COVID-19 ECONOMIC INJURY DISASTER LOAN APPLICANTS ON THE U.S. DEPARTMENT OF THE TREASURY'S DO NOT PAY LIST (June 4, 2024).

eligibility for participants.[582] During the PUA's first nine months of extended eligibility, claimants were able to self-certify their prior employment or self-employment without any documentation to receive funds.[583] Department of Labor Inspector General Larry D. Turner, testified that states were not prepared for the volume of UI claims and struggled to implement the new programs.[584] Specifically, the PUA program had control weaknesses that may have facilitated more improper payments.[585]

The ETA, tasked with providing guidance to states regarding improper payments, notified multiple states regarding control issues with the PUA form. One state did not include the required questions confirming that claimants are able and available to work while another state did not have a procedure in place for re-determining the claimant's weekly benefits if the claimants did not provide proof of earnings or insufficient proof.[586] These states responded to the issue raised by the ETA, but more than $25 billion in PUA benefits were already paid out to claimants that provided insufficient information on their application.[587]

FINDING:	Federal and State Agencies Lacked Up-to-Date Financial Management Systems, Failing to Meet Federally Mandated Modernization Requirements, Leading to Billions of Dollars of American Taxpayer Money Improperly Paid or Stolen.

The Council of the Inspectors General on Integrity and Efficiency CIGIE identified major problems in agencies IT security including that it lacked the ability to prevent cyberthreats and phishing attempts.[588] Integrated, functional, and secure data systems are essential for effective fraud and risk management.[589] Agencies' IT systems were unable to facilitate fraud detection and recovery.[590]

According to the Fraud Risk Framework, a leading practice in fraud data analytics is to conduct data mining and matching, including cross-checking of data using external data sources to validate information.[591] This includes the DNP list, which had its own flaws and lacked sufficient information to conduct oversight.

Most federal agencies at the time of the pandemic still had legacy IT systems in place to catch and control improper payments.[592] In May 2021, DOL IG identified various legacy IT systems still in place which was one of the main causes of the DOL's inability to detect waste,

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[582] U.S. Dep't of Labor, *supra* note 455.
[583] *Id.*
[584] *Id.*
[585] *Id.*
[586] *Id.*
[587] *Id.*
[588] PANDEMIC RESPONSE ACCOUNTABILITY COMMITTEE, TOP CHALLENGES FACING FEDERAL AGENCIES: COVID-19 EMERGENCY RELIEF AND RESPONSE EFFORTS AS REPORTED BY OFFICES OF INSPECTOR GENERAL ACROSS GOVERNMENT (June 2020).
[589] Examining Federal COVID-era Spending and Preventing Future Fraud: Hearing Before Subcomm. on Emerging Threats and Spending Oversight, Senate Homeland Security and Gov't Affairs Comm., 118th Cong. 1, (Nov. 1, 2023) (Testimony of Rebecca Shea, Dir., Forensic Audits and Investigative Service).
[590] *Id.*
[591] *Id.*
[592] *Id.*

fraud, and abuse int UI programs, including PUA.[593] These legacy systems did not have the ability to perform cross-matches for such a large volume of claims, posing a risk to claimants as their PII could become more easily accessible to criminals targeting UI.

Legacy IT systems also made it difficult for many states to prevent cybersecurity attacks or the use of fraudulently obtained information. DOL IG officials stated that some state IT systems were not equipped to handle the volume of claims, and some may not have been compatible with the National Association of State Workforce Agencies UI Integrity Center's Integrity Data Hub resources.[594] Even though a participation agreement between states was established, there was no way to verify that that participants were using the resources.

Stolen PII also played a role in large-scale identity fraud during the pandemic, providing a source for fraudsters. A Nigerian fraud ring took advantage of this lapse to commit large-scale fraud in Washington, North Carolina, Massachusetts, Rhode Island, Oklahoma, Wyoming, and Florida.[595] These states were subject to vulnerabilities based off their outdated IT systems allowing for transnational crimes against traditional and pandemic-related UI programs.[596]

[593] *Id.*
[594] *Id.*
[595] *Id.*
[596] *Id.*

The Implementation or Effectiveness of Any Federal Law or Regulation Applied, Enacted, or Under Consideration to Address the Coronavirus Pandemic and Prepare for Future Pandemics

I. Overreliance on the World Health Organization

The WHO is the most recognized global public health institution. As a specialized agency within the UN, the WHO's mandate is to "act as the directing and coordinating authority on international health work" within the UN system.[597] The overarching mission of the WHO is "attainment by all peoples of the highest possible level of health,"[598] and is achieved via (1) providing technical assistance to member states, (2) setting international health standards and providing guidance, and (3) coordinating and supporting international responses to health emergencies.[599]

Yet, while the WHO is supposed to support the entire world, during the COVID-19 pandemic, it appeared to protect its relationship with the CCP. The WHO was misinformed, denied access to China, and was used as cover for CCP's reckless actions. At a time when the globe was turning to the WHO for leadership and advice, the WHO's actions showed that it did not support all its members equally. What was seen was an organization that, rather than serving all of humankind, became beholden to and entrapped in politics.

The Director-General of the WHO can make a formal declaration of a "public health emergency of international concern," [hereinafter "PHEIC"] which can immediately implement action to attempt to stop or slow the spread of the PHEIC.[600] A PHEIC is defined as "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response."[601] These are situations that are serious, sudden, unusual or unexpected; carry implications for public health beyond the affected State's border; and may require immediate international action.[602]

When a PHEIC is declared, the WHO issues guidance as to how Member-States should respond to the emergency, which can include restrictions on travel and trade.[603] Declaring a

[597] Constitution of the World Health Organization (Nov. 1, 1946) (The WHO has 194 Member-States, all Members of the UN, except for Liechtenstein).
[598] United Nations Academic Impact, WORLD HEALTH ORG.
[599] Lawrence O. Gostin, *COVID-19 Reveals Urgent Need to Strengthen the World Health Organization*, JAMA HEALTH FORUM (Apr. 30, 2020).
[600] Emergencies: International health regulations and emergency committees, WORLD HEALTH ORG.
[601] *Id.*
[602] *Id.* (The WHO has declared six PHIECs: 2009 swine flu (H1N1) epidemic; 2014 in reaction to reversal of progress in polio; 2014 Ebola outbreak; 2016 Zika virus; 2019 Ebola; and 2020 COVID-19.)
[603] CRF.org Editors, *What Does the World Health Organization Do?*, COUNCIL ON FOREIGN RELATIONS (last updated June 2, 2022).

PHEIC is intended to speed up the rate of international action and even encourages research on the disease in question.[604] It is a formal declaration of a "red alert" to the world.[605]

The WHO has two primary sources of revenue, assessed contributions (set amounts expected to be paid by Member-State governments) and voluntary contributions (other funds provided by Member-States and private organizations).[606] Most assessed contributions are considered core funding, which are flexible funds used to cover general expenses and program activities.[607] Voluntary contributions are specialized funds which can be earmarked by donors for certain activities.[608]

The U.S. is historically the single largest contributor to the WHO.[609] The assessed contributions of the U.S. remained fairly stable between fiscal year (FY) 2014-2023, fluctuating between $110 million and $123 million.[610] U.S. voluntary contributions for specific projects or activities varied to reflect changing policies and/or support during international crisis. Voluntary contributions ranged from a low of $102 million in FY 2014 to a high of $402 million in FY 2017.[611]

Figure 2
U.S. Contributions to the World Health Organization (WHO), by Type of Contribution, FY 2014-FY 2023 (in millions)
Assessed
Voluntary
Voluntary contribution not yet available
$212
$102
$110
$438
$324
$114
$341
$228
$113
$513
$402
$111
$389
$278
$111
$421
$319
$102
$163
$105
$58
$583
$380
$203
$433
$311
$122
$108
$108
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
NOTE: *FY 2022 and FY 2023 are estimates. 2021 assessed contributions include approximately $80 million in funding provided toward outstanding arrears. 2022 voluntary contribution total may not capture the full U.S. voluntary contribution during this FY. * indicates 2023 voluntary contribution total is not yet available publicly from the U.S. government. WHO reports that the 2022-2023 biennium voluntary contribution from the U.S. totals $974 million as of April 2023 (see http://open.who.int/2022-23/contributors/contributor?name=United%20States%20of%20America). Does not include contributions to the Pan American Health Organization (PAHO).
SOURCE: KFF analysis of data from State Department Reports to Congress on U.S. Contributions to International Organizations, State Department budget materials, WHO Budget Sources on Voluntary and Assessed Contributions https://www.who.int/about/funding and http://open.who.int/2022-23/contributors/contributor, www.foreignassistance.gov, and KFF communication with OMB and HHS officials. • PNG
KFF

Apart from the assessed contributions from Member-States, the WHO is funded through private organizations through voluntary contributions.[612] These voluntary contributions are

[604] Mara Pilinger, *WHO declared a public health emergency about Zika's effects. Here are three takeaways*., THE WASH. POST (Feb. 2, 2016).
[605] *Id.*
[606] Financing of 2022-2023 Biennium, WORLD HEALTH ORG.
[607] *Id.*
[608] *Id.*
[609] *Id.*
[610] *The U.S. Government and the World Health Organization*, KFF (Jun. 13, 2024) (With the exception of 2020 when the Trump administration suspended financial support, and in 2021 when the Biden administration reestablished relations.).
[611] *Id.*
[612] *Id.*

specialized funds that can be earmarked by the individual donors for specific activities. In the current 2022-2023 budget, the total assessed contributions were 12.1 percent of the total revenue[613] (or approximately $956.9 million) and the total voluntary contributions were 87.5 percent (or approximately $6.92 billion).[614] For the 2020-2021 budget, the top five specified voluntary contributions were: Germany – $952 million; Bill & Melinda Gates Foundation - $592 million; U.S. – $447 million; GAVI Alliance – $413 million; and the United Kingdom of Great Britain and Northern Ireland – $367 million.[615]

The WHO exists for the protection of all. Yet in the time of the greatest global crisis, it did not deliver on its promises.

FINDING:	The World Health Organization Failed to Uphold Its Mission and Caved to Chinese Communist Party Pressure.

The WHO claims to "work worldwide to promote health, keep the world safe, and serve the vulnerable."[616] More specifically, regarding health emergencies, the WHO claims to:

- "Prepare for emergencies by identifying, mitigating and managing risks.
- Prevent emergencies and support development of tools necessary during outbreaks.
- Detect and respond to acute health emergencies.
- Support delivery of essential health services in fragile settings."[617]

The WHO's response to the COVID-19 pandemic was an abject failure. The Organization failed to satisfy all of the above stated goals.

Throughout the pandemic, the WHO shied away from placing any blame on the CCP. Dr. Tedros even went so far as to praise the CCP's "transparency" during the crisis, when, in fact, the regime consistently lied to the world by underreporting China's actual infection and death statistics.[618] During the pandemic, the WHO repeatedly relied on false information from the CCP.

The WHO Ignored Taiwan Despite It Warning of COVID-19 in December 2019

The WHO disregarded warnings from Taiwan of a burgeoning virus because of pressure from China. From 2009 to 2016, Taiwan was an observer in the WHO under the name "Chinese

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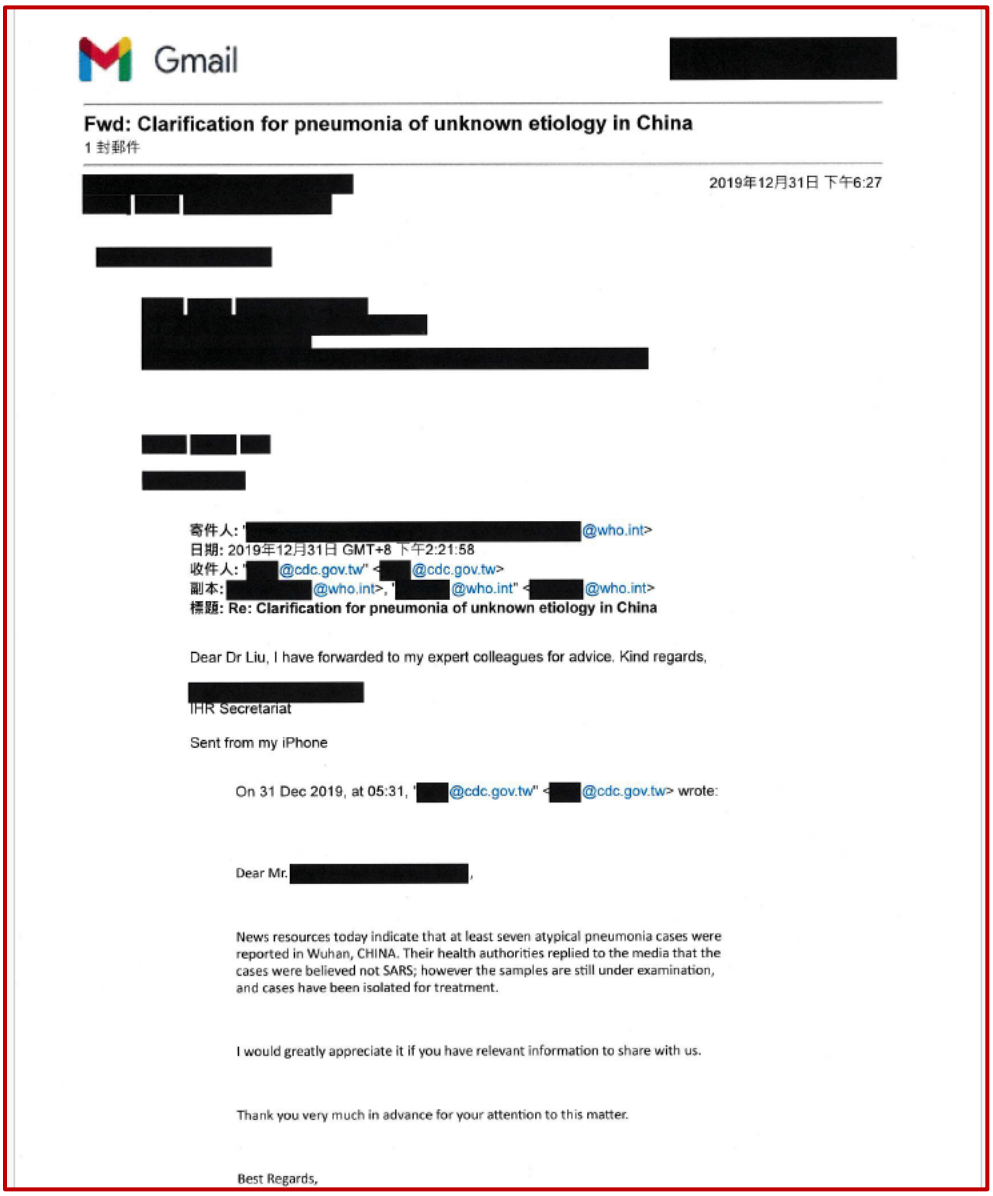
[613] *Id*. (updated Jun. 13, 2024).
[614] *Id.*
[615] *Voluntary contributors – Specified*, WORLD HEALTH ORG.
[616] *What we do,* WORLD HEALTH ORG.
[617] *Id.*
[618] The Editorial Board, *World Health Coronavirus Disinformation*, THE WALL STREET JOURNAL (Apr. 5, 2020); Nick Wadhams & Jennifer Jacobs, *China Concealed Extent of Virus Outbreak, U.S. Intelligence Says*, BLOOMBERG (Apr. 1, 2020).

Taipei."[619] Yet, the CCP has consistently blocked any form of engagement, ensuring the WHO does not formally recognize Taiwan as a Member-State. This lack of recognition led to these warnings from Taiwan being substantially ignored.

Taiwan notified the WHO as early as December 31, 2019, asking for more information about atypical pneumonia cases reported in Wuhan.[620] The WHO never followed up with information.



Gmail [redacted]

Fwd: Clarification for pneumonia of unknown etiology in China

1 封郵件

[redacted] 2019年12月31日 下午6:27

[redacted]

寄件人: "[redacted]@who.int>
日期: 2019年12月31日 GMT+8 下午2:21:58
收件人: "[redacted]@cdc.gov.tw" <[redacted]@cdc.gov.tw>
副本: [redacted]@who.int>, "[redacted]@who.int" <[redacted]@who.int>
標題: Re: Clarification for pneumonia of unknown etiology in China

Dear Dr Liu, I have forwarded to my expert colleagues for advice. Kind regards,

[redacted]
IHR Secretariat

Sent from my iPhone

On 31 Dec 2019, at 05:31, "[redacted]@cdc.gov.tw" <[redacted]@cdc.gov.tw> wrote:

Dear Mr. [redacted],

News resources today indicate that at least seven atypical pneumonia cases were reported in Wuhan, CHINA. Their health authorities replied to the media that the cases were believed not SARS; however the samples are still under examination, and cases have been isolated for treatment.

I would greatly appreciate it if you have relevant information to share with us.

Thank you very much in advance for your attention to this matter.

Best Regards,

Then Taiwanese Vice President Chen Chien-Jen, a renowned scientist with a doctorate in epidemiology from Johns Hopkins University who oversaw the SARS outbreak in Taiwan in

[619] Jonahtan Herington & Kelley Lee, *The limits of global health diplomacy: Taiwan's observer status at the world health assembly*, GLOBALIZATION AND HEALTH (Oct. 1, 2014).
[620] E-Mail from IHR Secretariat, to Dr. Liu (Dec. 31, 2019, 02:21).

2003, stated in an interview that had Taiwan been a member of the WHO, it would have been even better prepared for countermeasures against COVID-19.[621]

The initial mismanagement of the COVID-19 pandemic not only potentially caused the further spread of the virus, but it created a situation where people lost trust in the global public health organization. The IHR requires mutual communication, yet when it was time to test the strength of this trust, the WHO did not care to use their own policy, rather playing politics and ensuring their relationship with the CCP remained intact.

The WHO Denied Human-to-Human Spread of COVID-19 Based Solely on CCP Propaganda

On January 14, 2020, the WHO tweeted that "[p]reliminary investigations conducted by Chinese authorities have found no clear evidence of human-to-human transmission of the novel coronavirus."[622]

World Health Organization (WHO)
@WHO
Preliminary investigations conducted by the Chinese authorities have found no clear evidence of human-to-human transmission of the novel #coronavirus (2019-nCoV) identified in #Wuhan, #China.

These "preliminary investigations" in actuality included the CCP jailing any doctor that disseminated any information about COVID-19 that was not first cleared through state-run media.[623] U.S. intelligence sources have since discovered that the CCP covered-up and lied about the extent of the outbreak.[624] On January 23, 2020, the WHO finally recognized that human-to-human spread was occurring, a month later than the first warnings.[625]

The WHO Prolonged Naming COVID-19 a PHEIC and Pandemic Because the CCP Insisted the Spread was Under Control

By the time the WHO declared COVID-19 a PHEIC on January 30, 2020, the disease had infected almost 10,000 and killed almost 1,000 people in 19 different countries.[626] It was

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[621] Javier C. Hernandez & Chris Horton, *Taiwan's Weapon Against Coronavirus: An Epidemiologist as Vice President*, THE N.Y. TIMES (May 9, 2020).
[622] World Health Organization (@WHO), Twitter (Jan. 14, 2020) *available at* https://twitter.com/WHO/status/1217043229427761152?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed&ref_url=https%3A%2F%2Fwww.foxnews.com%2Fworld%2Fworld-health-organization-january-tweet-china-human-transmission-coronavirus.
[623] Jim Geraghty, *Whom Does WHO Trust?*, NATIONAL REVIEW (Mar. 20, 2020).
[624] Wadhams, *supra* note 618.
[625] Francois Godement, *Fighting the Coronavirus Pandemic: China's Influence at the World Health Organization*, INSTITUT MONTAIGNE (Mar. 23, 2020).
[626] *Deaths surpass 200, and State Department Urges Against Travel to China*, THE N.Y. TIMES (Jan. 30, 2020).

reported that the delay in PHEIC declaration was a result of intense pressure from the CCP.[627] According to both the U.S. Central Intelligence Agency and the German Bundesnachrichtendienst [hereinafter "BND'], on January 21, 2020 the CCP threatened to cease participation in all international COVID-19 efforts if the WHO declared a PHEIC.[628] While making the PHEIC declaration, Dr. Tedros stated, "China is to be congratulated for the extraordinary measures it has taken to contain the outbreak."[629] The BND concluded that the WHO's delay in declaring the PHEIC wasted approximately four to six weeks of the potential global response to the COVID-19 pandemic.[630]

The WHO Delayed and Denigrated Serious Countermeasures, Like Travel Restrictions, Because of CCP Pressure

Despite declaring COVID-19 a PHEIC and extensive evidence of transmission through travel, the WHO insisted other countries not restrict travel or trade to or from China.[631] On January 31, 2020, President Trump came under intense criticism when he barred travel from China; an order called "xenophobi[c]" by then Presidential candidate Biden.[632] As Dr. Fauci testified on July 31, 2020, in comparison to the WHO's inaction, President Trump's decision to restrict travel from China saved lives.

Dr. Anthony Fauci (July 31, 2020)

Q. Dr. Fauci, let me ask you about some of the decisions that you worked with President Trump on and the whole team did. I know when you go back to the beginning of this, the China ban was very heavily discussed. Were you involved in working with President Trump on deciding to ban flights from China?

A. Yes, sir, I was.

Q. Do you agree with that decision?

A. I do.

Q. Do you think that decision saved lives, Dr. Fauci?

[627] Sarah Boseley, *China's handling of coronavirus is a diplomatic challenge for WHO*, BLOOMBERG (Feb. 18, 2020).
[628] Naveed Jmali & Tom O'Connor, *Exclusive: As China Hoarded Medical Supplies, the CIA Believes it Tried to Stop the WHO from Sounding the Alarm on the Pandemic*, NEWSWEEK (May 12, 2020).
[629] Sarah Boseley, *WHO declares coronavirus a global health emergency*, THE GUARDIAN (Jan. 30, 2020).
[630] Matthew Strong, *China asked WHO to cover up coronavirus outbreak: German intelligence service*, TAIWAN NEWS (May 05, 2020).
[631] Yasufumi Saito, Andrew James, & Rosa de Acosta, *High-Speed Trains, International Flights: How the Coronavirus Spread*, THE WALL STREET JOURNAL (Mar. 5, 2020); Boseley, *supra* note 627.
[632] Dan McLaughlin, *Trump Could Have Restricted Travel Further*, NATIONAL REVIEW (Apr. 7, 2020).

A. Yes, I do.[633]

Dr Fauci, however, could have quelled the unwarranted criticism that the travel restrictions were xenophobic if he had forcefully and publicly supported President Trump's decision.

Between December 31—when cases were first reported—and January 31, more than 430,000 people were on direct flights from China to the U.S.[634] If the CCP had been more transparent and the WHO acted with integrity, fewer COVID-19 cases would have entered the U.S.

The WHO Continued to Praise CCP Failed Efforts to Combat the Pandemic, Despite a Globally Recognized the Cover-Up

The WHO routinely praised the CCP's efforts to combat the spread of COVID-19 despite multiple reports that the CCP engaged in a massive disinformation campaign.[635] According to a U.S. intelligence community report, the CCP severely underreported both its total number of cases and deaths caused by COVID-19.[636] The CCP continually altered their reporting methodology which, at different points, left out individuals who tested positive but were asymptomatic—despite their ability to remain contagious.[637] The CCP also gagged doctors and journalists that attempted to speak the truth about the severity of COVID-19.[638] Dr. Tedros said the CCP should be "praised" for these manipulative tactics; tactics frowned upon worldwide.[639]

The WHO Failed to Condemn the CCP's Aggressive Tactics Against Whistleblowers, Journalists, and Americans

The CCP is a known human rights offender, including by silencing or "disappearing" dissenters, journalists, and researchers that go against the CCP's narrative.

Dr. Ai Fen was the first Chinese doctor to receive a laboratory test of a possible SARS-CoV type virus in Wuhan. Dr. Ai then sent the laboratory test results to a group of eight other Chinese scientists, including Dr. Li Wenliang. These scientists expressed grave concern over the test results and began warning others of the novel virus—later to be named COVID-19. As a result, they were all harassed by CCP officials for "spreading rumors" regarding the novel COVID-19 outbreak.[640]

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[633] The Urgent Need for a National Plan to Contain the Coronavirus: Hearing Before the Select Subcomm. on the Coronavirus Crisis, H. Comm. on Oversight & Reform, 116th Cong (July 31, 2020).
[634] Derrick Bryson Taylor, *A Timeline of the Coronavirus Pandemic*, THE N.Y. TIMES (Apr. 7, 2020).
[635] *WHO chief praises China's virus fight, urges more from world*, ASSOCIATED PRESS (Feb. 15, 2020).
[636] Wadhams, *supra* note 618.
[637] *Id*.
[638] *Whom Does WHO Trust?*, *supra* note 623.
[639] Boseley, *supra* note 627.
[640] *Li Wenliang: Coronavirus kills Chinese Whistleblower doctor*, BBC (Feb. 7, 2020).

On January 1, 2020, Dr. Ai ordered her staff to wear masks to combat the spread and was immediately called in front of her hospital's disciplinary board.[641] She was then accused of "spreading rumors" and "damag[ing] the stability of Wuhan."[642] The disciplinary board went further and banned Dr. Ai and her staff from publicly discussing the virus.[643] Unfortunately, because of the CCP's efforts to silence Dr. Ai, multiple members of her medical team became sick and later died.

On January 3, 2020—four days after Dr. Li warned of a novel virus—he was forced to sign a letter accusing him of "making false statements" that "severely disturbed the social order" by the Wuhan Public Security Bureau.[644] This punishment and the harassment of the seven other doctors was publicly broadcast on CCP state media to deter any other whistle-blowers from coming forward.[645] Dr. Li was allowed to return to work but consequently contracted COVID-19 five days later, on February 7, died of complications from COVID-19.[646]

On January 3, 2020, the CCP arrested eight people for "publishing or forwarding false information without verification."[647] The CCP then "issued a warning that anyone caught using social media to share coronavirus information obtained from anywhere, but state-run media or organizations would face between three and seven years in jail."[648]

Additionally, the CCP took the unprecedented step of expelling U.S. journalists reporting on the beginnings of the COVID-19 pandemic from China.[649] The CCP expelled at least 13 journalists, including correspondents from *The New York Times, Wall Street Journal,* and *Washington Post*.[650]

Further, according to the FBI and the U.S. Cybersecurity and Infrastructure Security Agency, the CCP instituted a cyber espionage campaign in an attempt to steal sensitive U.S. research related to COVID-19 vaccines and treatments.[651] These attacks were a direct assault on U.S. public health.

And finally, according to the CCP aligned *Global Times*, the CCP was considering "punitive measures" against multiple state and federal U.S. lawmakers.[652] In an unprecedented

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[641] Jeremy Page*, et al., How the WHO's Hunt for Covid's Origins Stumbled in China*, WALL STREET JOURNAL (Mar. 17, 2021) [hereinafter "Page"].
[642] *Id.*
[643] *Id.*
[644] *Id.*
[645] *China didn't warn public of likely pandemic for 6 key days*, ASSOCIATED PRESS (Apr. 15, 2020).
[646] *Li Wenliang: Coronavirus kills Chinese Whistleblower doctor*, BBC (Feb. 7, 2020).
[647] Jim Geraghty, *Whom Does WHO Trust?,* NATIONAL REVIEW (Mar. 20, 2020).
[648] *Id.*
[649] Tony Munroe, *et al., China expels American journalists as spat with U.S. escalates*, REUTERS (Mar. 18, 2020).
[650] *Id.*
[651] Public Service Announcement, Federal Bureau of Investigation & Cybersecurity and Infrastructure Security Agency People's Republic of China (PRC) Targeting of COVID-19 Research Organizations (May 13, 2020); Gordon Lubhold & Dustin Volz, *U.S. Says Chinese, Iranian Hackers Seek to Steal Coronavirus Research*, THE WALL STREET JOURNAL (May 14, 2020).
[652] Chen Qingqing & Li Sikun, *China targets GOP hawks, US forms, states over lawsuits*, GLOBAL TIMES (May 14, 2020).

and abhorrent step, the CCP said it will "strike back" at attempts from the U.S. government to ascertain the origins of COVID-19 and go beyond sanctions to make U.S. lawmakers "feel painful."[653] For example, the Chinese Ambassador to the U.S. expressed its "grave concern" regarding the Select Subcommittee's investigation.[654] This is just another example of China and the CCP obfuscating their wrongdoing during the beginnings of this pandemic.

Shockingly, the WHO has not acknowledged or supported the brave actions by these scientists and reporters who blew the whistle against the oppressive CCP regime and warned the world about this deadly pandemic. Instead of praising their efforts to save lives, the WHO routinely promoted the CCP regime's disinformation.

The WHO Posted False Information Regarding the Origins and Notification of COVID-19's Emergence

On April 9, 2020, Committee on Oversight and Reform Republicans wrote to Dr. Tedros regarding the WHO's failed response to the COVID-19 pandemic.[655] On June 15, 2020, more than two months after receipt of the letter, Dr. Tedros provided a formal response.[656] This response was wholly incomplete and contained at least one false statement.[657]

From as early as April 27, 2020, the WHO included a COVID-19 response timeline on its public website.[658] This timeline originally stated that on December 31, 2019 the "Wuhan Municipal Health Commission, China, reported a cluster of cases of pneumonia in Wuhan, Hubei Province" to the WHO.[659] This is also what Dr. Tedros told the Committee in his June 15, 2020 letter and maintained on the WHO's website until June 29, 2020.[660] On April 20, 2020, during a virtual press conference, Dr. Tedros even said: "[t]he first report came from Wuhan, from China itself."[661]

However, the WHO chose to quietly contradict these claims by posting an "updated" timeline to its official website.[662] Then, on June 30, 2020, the above reference was quietly scrubbed from the website timeline. The timeline now states that the "WHO's Country Office in

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[653] Paul D. Shinkman, *China Threatens to Sanction U.S. Politicians for Coronavirus Criticism*, U.S. NEWS & WORLD REPORT (May 14, 2020).
[654] Adam Sabes, *Chinese Embassy emails House Republican staff expressing 'grave concern' with COVID-19 origins hearing*, FOX NEWS (Apr. 15, 2023).
[655] Letter from Jim D. Jordan, *et. al.*, Ranking Member, H. Comm. on Oversight & Reform, to Dr. Tedros Adhanom Ghebreyesus, Director-General, World Health Org. (Apr. 9, 2020).
[656] Letter from Dr. Tedros Adhanom Ghebreyesus, Director-General, World Health Org., to Jim D. Jordan, Ranking Member, H. Comm. on Oversight & Reform (June 15, 2020).
[657] *Id.*
[658] Statement, World Health Org., Archived: WHO Timeline – COVID-19 (last updated June 29, 2020), *available at* https://www.who.int/news-room/detail/27-04-2020-who-timeline---covid-19.
[659] *Id.*
[660] Letter from Dr. Tedros Adhanom Ghebreyesus, Director-General, World Health Org., to Jim D. Jordan, Ranking Member, H. Comm. on Oversight & Reform (June 15, 2020).
[661] *Virtual Press Conference.* WORLD HEALTH ORG. (Apr. 20, 2020) *transcript available at* https://www.who.int/docs/default-source/coronaviruse/transcripts/who-audio-emergencies-coronavirus-press-conference-20apr2020.pdf.
[662] Adam Kredo, *China Never Reported Existence of Coronavirus to World Health Organization*, THE WASH. FREE BEACON (July 2, 2020).

the People's Republic of China (PRC) picked up a media report…on cases of 'viral pneumonia' in Wuhan, PRC."[663] In actuality, the "media report" was information posted to a U.S. website from doctors working at the epicenter of the pandemic.[664] This revelation confirms that the CCP failed to notify the WHO of the outbreak. This failure is a violation of the IHR for which the CCP must be held accountable.[665] By refusing to disclose the truth, the WHO made an affirmative decision to shield the CCP from accountability.

FINDING:	The Chinese Communist Party Violated Articles Six and Seven of the International Health Regulations with No Repercussions.

The CCP violated IHR Articles Six and Seven and needs to be held accountable.

Article 6 of the IHR says that "[e]ach State Party shall notify WHO…within 24 hours…of all events which may constitute a public health emergency of international concern."[666] In order for an outbreak to require notification it must: (1) have serious public health consequences, (2) be unusual or unexpected, (3) have risk of international spread, and (4) pose significant risk to international trade.[667] COVID-19 met all these criteria well before the WHO was formally notified of the outbreak by China. Further, Article 7 of the IHR states that if a "State Party has evidence of an unexpected or unusual public health event…it shall provide to WHO all relevant public health information."[668] The CCP failed to notify the WHO in a timely manner and subsequently concealed valuable information—harming the global response and leading to unnecessary illness and death.

According to reports from Hong Kong, the CCP identified cases of COVID-19 going all the way back to November 17, 2019—more than a month before the WHO was publicly notified.[669] On December 27, 2019, Dr. Zhang Jixian, a doctor with the Hubei Provincial Hospital Integrated Chinese and Western Medicine, told CCP health authorities that the disease was caused by a novel coronavirus—three days before the WHO was publicly notified.[670] Doctors were ordered not to disclose any information about the unidentified virus to the public.[671] This delay in public notification is in violation of Article 6 of the IHR and led to a delay in global response.

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[663] Listings of WHO's Response to COVID-19, WORLD HEALTH ORG. (last updated June 29, 2021), *available at* https://www.who.int/news-room/detail/29-06-2020-covidtimeline.
[664] *Id;* Adam Kredo, *China Never Reported Existence of Coronavirus to World Health Organization*, THE WASH. FREE BEACON (July 2, 2020).
[665] INTERNATIONAL HEALTH REGULATIONS, 2nd, at 12 WORLD HEALTH ORG. (2005);
Matthew Lee, *Trump US notifies UN of withdrawal from World Health Organization*, THE ASSOCIATED PRESS (July 7, 2020).
[666] IHR, *supra* note 665.
[667] *Id.* at 44-46.
[668] *Id.* at 12.
[669] Josephine Ma, *Coronavirus: China's first confirmed COVID-19 case traced back to November 17*, SOUTH CHINA MORNING POST (Mar. 13, 2020); Statement, World Health Organization, WHO Timeline-COVID-19 (last updated Apr. 27, 2020).
[670] *Id.*
[671] *Id.*

Additionally, Dr. John MacKenzie, WHO's emergency committee adviser, admitted that the WHO was "misled" about the outbreak.[672] He stated by the time the CCP notified the WHO on December 31, the CCP had already sequenced the virus genome—the first step to creating an accurate test and developing medical countermeasures—but did not share the sequencing with the WHO until January 12, in violation of Article 7 of the IHR.[673]

This was confirmed by Dr. Farrar, in his book *Spike: The Virus vs The People The Inside Story*, and Dr. Daszak in a transcribed interview before the Select Subcommittee.

Dr. Peter Daszak (November 14, 2023)

Q. Do you recall when China first officially reported what would become COVID-19?

A. It was in early January, from my recollection. I mean, we heard about it 18 earlier than that through unofficial channels.

Q. When did you first hear about it?

A. I think December the 30th or the 31st. It's a matter of record. I put out a tweet, I think very late on the 31st, New Year's Eve. But I think I heard about it the day before. And, you know, you hear about these rumors all the time. "Oh, there's an outbreak here, there's an outbreak there." Your first response is, well, verify, to quote Ronald Reagan. So we managed to get hold of folks in China and ask what they knew, what are these rumors. And we were told on the day before New Year's Eve, to my recollection, that there was a new coronavirus percent different to SARS, which was strangely accurate information.

…

Q. Okay. Do you recall when the genome was publicly released?

A. I think it was the 9th or the 12th of January.[674]

For potentially more than two weeks, the CCP held the key to the global response but refused to share it.

The CCP intentionally delayed notification of COVID-19 and concealed important health information in violation of Articles 6 and 7 of the IHR. These actions demonstrate the CCP's complete lack of respect for the global public health community.

[672] Stephen Buranyi, *The WHO v coronavirus: why it can't handle the pandemic*, THE GUARDIAN (Apr. 10, 2020).
[673] *Id.*
[674] Daszak TI, *supra* note 253, at 169-170, 173.

FINDING:	The World Health Organization's Report Regarding the Origins of COVID-19 Was Incomplete, Misleading, and Parroted Chinese Communist Party Propaganda.

Apart from the initial mismanagement of the virus, the WHO produced a report on the origins of COVID-19 that did nothing but continue the CCP's propaganda.[675] The WHO attempted to organize an investigation into the origins of the virus, yet from the very beginning it was evident the CCP was completely in control.

The "Terms of Reference for the China Part" [hereinafter "Terms of Reference"] was a document that laid the ground rules for the WHO's investigation. These terms were inherently flawed, provided significant discretion to the CCP, and continued to parrot CCP propaganda.[676] Some examples included:

- Supporting CCP propaganda by stating the investigation would also evaluate the "possibility the virus may have silently" started outside of Wuhan.

- Dodging responsibility by "build[ing] on existing information and augment, rather than duplicate, ongoing [CCP]…efforts."

- Phony scientific independence by giving the CCP final right of refusal on the "composition of the international team."[677]

With these restrictions baked into the Terms of Reference, it was near impossible for any review of the origins of COVID-19 conducted by the WHO to bear fruit.

In January 2021, an international team traveled to Wuhan, China to review evidence of when and how the virus might have emerged.[678] In March 2021, the WHO team released a report, entitled "WHO-Convened Global Study of Origins of SARS-CoV-2: China Part," [hereinafter "WHO Report"] outlining four possible origin scenarios:

1) "direct zoonotic spillover is considered to be a possible-to-likely pathway;

2) introduction through an intermediate host is considered to be a likely to very likely pathway;

3) introduction through cold/food chain products is considered a possible pathway; [and]

[675] WHO-convened Global Study of the Origins of SARS-CoV-2, WORLD HEALTH ORG. (Nov. 5, 2020).
[676] WHO-convened Global Study of the Origins of SARS-CoV-2: Terms of Reference for the China Part (July 31, 2020).
[677] *Id.*
[678] Smriti Mallapaty, *WHO abandons plans for crucial second phase of COVID-origins investigation*, NATURE (Mar. 3, 2020).

4) introduction through a laboratory incident was considered to be an extremely unlikely pathway."[679]

Yet, many, including the U.S., U.K., Australia and Canada, sharply criticized the WHO Report.[680] Experts stated the scientists weren't provided with access to complete, original data and samples; full access to interviews; and access to any and all laboratories they wished to tour.[681] Even members of the WHO team stated the report was not adequate. Dr. Ben Embarek, a WHO expert who led the WHO mission to Wuhan, reiterated there were areas his team had difficulty getting down to the raw data in China, adding that the data would need to be reexamined in the next phase of the study.[682] He also stated the report "only scratched the surface," of their understandings of the origins of COVID-19.[683]

Prominent U.S. public health officials, such as Dr. Fauci, publicly denounced the report. In March 2021, on *Face The Nation*, Dr. Fauci stated, "[t]here was a lot of restrictions on the ability of the people who went there to really take a look…[I] have some considerable concerns about that."[684] Further senior officials, including President Biden's Secretary of State Mr. Antony Blinken, similarly criticized it stating, "[w]e've got real concerns about the methodology and the process that went into that report, including the fact that the government in Beijing apparently helped to write it."[685]

It is no surprise the WHO Report did not receive a glowing reception from the global stage. To begin with, one of the conditions the CCP demanded in allowing the investigation to take place at all, was that they had full veto power over the inclusion of American scientists.[686] HHS submitted three expert candidates: a virologist who works on viruses that require study in high-security laboratories; a senior veterinarian; and a medical epidemiologist leading a program in global health studies.[687] All three were denied.

The only American on the WHO's team was Dr. Daszak, who prominent scientists acknowledged has significant conflicts of interest, due in part to his work with the WIV—the very laboratory the WHO group was supposed to be investigating.

Dr. Ian Lipkin (Apr. 6, 2023)

Q. The team was comprised of 17 international scientists and 17 Chinese scientists. There is only one American. It was Dr. Daszak

[679] *WHO-convened Global Study of Origins of SARS-CoV-2: China Part,* WORLD HEALTH ORG. (Jan. 14-Feb. 10 2021).
[680] Peter Beaumont, *UK and U.S. criticize WHO's Covid report and accuse China of withholding data*, THE GUARDIAN (Mar. 30, 2021).
[681] *Id.*
[682] *Id.*
[683] *Id.*
[684] Transcript, Anthony Fauci, *Face the Nation* (Mar. 28, 2021).
[685] Javier C. Hernandez, *The U.S. is concerned about China's influence over a report on the pandemic's origins*, THE N.Y. TIMES (Mar. 29, 2021).
[686] Page, *supra* note 641.
[687] *Id.*

of EcoHealth Alliance. Do you think Dr. Daszak has conflicts of interest regarding the search for origins of COVID 19?

A. I do.

Q. Why?

A. Because he was – because he had ran an active research program at WIV.[688]

Dr. Anthony Fauci (Jan. 9, 2024)

Q. I'm going to ask your opinion now. He has obviously been intertwined with the Wuhan Institute for a long time, has made numerous public statements, has now -- over the past 3 years, we've seen numerous compliance issues with his grants. Do you think that he has a conflict of interest in investigating the origins question?

A. I believe that he could've saved himself a lot of trouble if he did.

Q. If he did disclose a conflict of interest?

A. Yeah, yeah, because he's obviously received a lot of flak about that and had doubts about his credibility on that. I think, retrospectively, thinking about it, he probably would've said it would have been a better idea to do.[689]

A significant restriction, was the CCP's complete control over every single aspect of the investigation team's itinerary and access to information. Upon arriving in Wuhan, the WHO team quarantined for two weeks in hotel rooms and were further restricted to certain areas of the hotel after quarantining.[690] The investigators were restricted from dining with their Chinese counterparts, a seemingly insignificant detail, yet denied the WHO team the opportunity to engage in informal, human-to-human, conversation that can provide invaluable information.[691]

In Wuhan, Chinese scientists stated they had reviewed the medical records of approximately 76,000 patients from more than 200 medical institutions.[692] When the WHO team requested raw numbers and data, Chinese scientists only presented analysis.[693] Of the 76,000 medical records examined, 92 patients from October, November, and early December 2019 curiously showed symptoms suggesting COVID-19, yet none tested positive for antibodies

[688] Lipkin TI, *supra* note 38, at 73-74.
[689] Fauci TI 2, *supra* note 81, at 2.
[690] Page, *supra* note 641.
[691] *Id.*
[692] *Id.*
[693] *Id.*

according to medical records.[694] The WHO team was not allowed to review any raw data or conduct their own analysis.[695]

The WHO Report's conclusion included four hypotheses: that the virus jumped directly from animal to human; it spread via some (one not identified) intermediate animal; it was transmitted via the food chain, especially frozen products; or it came from a laboratory.[696] These were concluded via a show of hands, in a room with Chinese counterparts—many of whom report directly to the CCP—that had already ruled out a lab accident and suggested the pandemic started somewhere outside of China.[697] The theory that the virus came from a lab was voted as "extremely unlikely" and wasn't recommended for further research.[698]

This was very clearly not a thorough, complete, or impartial investigation. The CCP Ministry of Foreign Affairs even admitted, "China firmly opposes certain countries' attempts to…hold China accountable."[699] Yet, even though the rest of the world understands this report is a sham, the CCP presents it as the definitive assessment concerning the origins of COVID-19. So much so, the Chinese Ambassador to the U.S. sent the Select Subcommittee a letter attempting to obstruct the Select Subcommittee's investigation into the origins of COVID-19, citing to the WHO origins report.[700]

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[694] *Id.*
[695] *Id.*
[696] *Id.*
[697] *Id.*
[698] *Id.*
[699] Ken Moritsugu, *China outlines COVID-origin findings ahead of WHO Report*, ABC NEWS (Mar. 26, 2021).
[700] E-Mail from Li Xiang, Counselor, Embassy of China in the United States of America, to Staff, Select Subcomm. on the Coronavirus Pandemic (May 3, 2023, 2:15 AM).

From: Li Xiang [redacted]
Sent: Friday, April 14, 2023 2:15 AM
To: [redacted]
Cc: [redacted]
Subject: About the upcoming hearing on COVID-19 origins

Dear [redacted],

I am Counselor Li Xiang with the Chinese Embassy in the US. I am reaching out to express our grave concern regarding the COVID-19 Origins hearing to be chaired by Congressman Wenstrupon next Tuesday. According to the announcement, the hearing is to examine "China's complicity in the COVID-19" crisis and hold China accountable. We firmly oppose it. and I would like to share with you our perspectives on this issue.

First of all, the origins-tracing is a complex matter of science. This study should be and can only be conducted jointly by scientists. Intelligence community, which is highly political in nature, cannot possibly produce anything objective or credible on such professional matter. We oppose "political tracing" or "intelligence tracing". We oppose any attempt to lable China esp. Wuhan as the origin of the virus before any concrete evidence is presented and conclusion is drawn collectively by the scientists all over the world. We oppose any political manuveur such as "verdict first, then comes trial".

Second, China values life and public health cause around the globe and is always ready to cooperate with other countries on origin tracing. "A laboratory origin of the pandemic was considered to be extremely unlikely" is a science-based, authoritative conclusion reached by the experts of the WHO-China joint mission after field trips to the lab in Wuhan and in-depth communication with researchers in 2021. It was accurately recorded in the mission's report and has received extensive recognition from the international community and the science community.

Third, the hearing just demonstrates that the US is going further and further down the wrong path. To simply blame others or find a scapegoat for its own failure and incompetence is the easiest thing to do, but it is neither responsible for the past nor helpful for the future.

We call on the US side to respect science and facts, refrain from targeting China in holding the above-mentioned hearings, and put a stop to the intelligence-led, politics-driven origins-tracing, and help promote international solidarity against the pandemic and global cooperation on science-based origins-tracing.

I look forward to having an in-depth discussion with you on COVID-19 or any other issue of mutual concern at any time.

LI Xiang
Counsellor
Embassy of China in the USA
Tel: [redacted]
Address: 3505 International Place NW, Washington DC 20008

FINDING:	The World Health Organization's Draft "Pandemic Treaty" Does Not Solve the Organization's Underlying Problems and May Affirmatively Harm the United States.

Unlike the World Trade Organization, the WHO has no real authority to sanction or otherwise pressure its Member-States. As *Lancet* editor Dr. Richard Horton said, "[t]he WHO has been drained of its power and resources. Its coordinating authority and capacity are weak. Its ability to direct an international response to a life-threatening epidemic is non-existent."[701] The only authority WHO leadership must enforce compliance is via public pressure. Illustrative of this point, when asked to name the countries who had "alarming levels of inaction," Dr. Mike Ryan, WHO's head of COVID-19 response, stated, "[y]ou know who you are, we don't criticize our member states in public."[702]

The COVID-19 pandemic was the worst global public health emergency since the inception of the WHO in 1948 and it further exposed the severe limitations of the IHR and the institutional limits of the WHO. The IHR is designed to achieve a higher level of global health security, but in the face of COVID-19, the IHR did not properly perform its management or supervision.[703]

Responding to the many calls of Member-States to strengthen the framework for future pandemics, a rare special session of the WHA convened in November 2021.[704] There, Member-States agreed "to establish…an intergovernmental negotiating body open to all Member States and Associate Members to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response."[705]

As of September 20, 2024, there was not a completed, presentable draft of a Pandemic Treaty.[706] As of the draft dated March 13, 2024, the overall goal of the Pandemic Treaty is to help "prevent, prepare for and respond to pandemics."[707] The provisions (still being negotiated) included definitions and principles, aspirational goals for improving pandemic preparedness and response capacities, and supply chain and logistics.[708] Some of the more contested and debated provisions include financing for pandemic preparedness and response, pathogen access and benefit sharing, intellectual property rights, technology transfer, and research and development for pandemic-related products.[709]

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[701] Stephen Buryani, *The WHO v coronavirus: why it can't handle the pandemic*, THE GUARDIAN (Apr. 10, 2020).
[702] *Id.*
[703] Myungsei Sohn, *The problem of International Health Regulations (IHR) in the process of responding to COVID-19 and improvements measures to improve its effectiveness*, JOURNAL OF GLOBAL HEALTH SCIENCE (Dec.13, 2021).
[704] Nick Cumming-Bruce, *W.H.O. members agree to begin talks on a global pandemic treaty*, THE N.Y. TIMES (Dec. 1, 2021).
[705] World Health Assembly, Second Special Session (Dec. 1, 2021).
[706] News Release, World Health Organization, Governments progress on negotiations for a pandemic agreement to boost global preparedness for future emergencies (Sept. 20, 2024).
[707] *Revised Draft of the negotiating text of the WHO Pandemic Agreement*, WORLD HEALTH ORG. (Mar. 13, 2024).
[708] *Id.*
[709] *Id*

The Pandemic Treaty does not address the weaknesses of the IHR. The WHO's refusal to hold the CCP accountable for violating the IHR is a major issue in protecting global public health.

Furthermore, there are specific U.S. concerns regarding enactment of any potential Pandemic Treaty. Throughout the ongoing negotiations, there have been questions about the transparency of the negotiations. There have been multiple closed-door negotiations resulting in large edits that are then presented to all Member-States. Further, it is not clear if this treaty will be ratified through the U.S. Senate or not. If the U.S. determines to enact a Pandemic Treaty, it must go through the required Senate approval process.

While a new pandemic, prevention, preparedness, and response treaty seems like a good idea in theory, on paper it falls short. The draft does little to address any of the shortfalls revealed in COVID-19. The WHO needs to be an organization that represents and protects the entire world. That requires a system of trust from both the Member-States to report and the WHO to protect, which proved not to be the case during the pandemic. Accordingly, Ambassador Nkengasong testified:

> **The Honorable John Nkengasong (December 13, 2023)**
>
> We fully agree with your opening remarks about the trust capital that is required to [deal] with global disease threats, and that comes with the ability to be fully transparent, to be accountable, to report in a timely fashion, and also to cooperate, and all of these elements were lacking in China's ability to cooperate with WHO and the world. And when you have a fast-moving respiratory disease like COVID, all of these elements are very important for the global health security.
>
> I think the burden is still on China, that for the past 3 years China has not been forthcoming the way it should be in working with WHO, working with us directly so that we just understand what the origin is of the virus is so that it can better prepare us for the future. As we have all said, it is a matter of time before we are faced with another threat, yes, so I think I fully agree with you that we need to build a trusting relationship that will enable us to be able to respond in a very timely fashion.[710]

[710] Reforming the WHO: Ensuring Global Health Security and Accountability: Hearing Before Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, 118th Cong., 1 (Dec. 13, 2023).

II. The Strategic National Stockpile Was Not Prepared to Address a Nationwide Viral Pandemic

The SNS is the U.S. stockpile of pharmaceutical drugs, medical products, and ancillary supplies.[711] Deployed at the discretion of the Secretary of HHS, these supplies supplement medical countermeasures needed by states, tribal nations, territories, and the largest metropolitan areas during public health emergencies.[712] Congress mandated the SNS in 1999, and since then it has provided resources during hurricanes, floods, bioterror events, and infectious disease outbreaks, including of course the COVID-19 pandemic.[713]

The SNS is a network of strategically placed, not publicly known, storehouses designed to supplement and resupply resources in a timely response to state and local public health agencies in the event of an emergency at anywhere and anytime within the U.S.[714] The SNS' purpose and task is to deliver medical supplies to communities within 12 hours of the decision to deploy the stockpile.[715]

In its current form, the mission of the SNS is to "provide for the emergency health security of the United States…in the event of a bioterrorist attack or other public health emergencies."[716] Between Fiscal Years (FY) 2015 and 2021, three-quarters of the non-COVID-19 supplies and budget were allocated to fighting just two threats: smallpox and anthrax.[717]

HHS provides a 24/7, 365 emergency contact for senior government officials to call when an emergency arises. Within approximately 15 minutes, SNS leadership, subject matter experts, and other federal agencies either gather for a conference call or direct the requestor to the appropriate technical experts.[718] The Office of the Assistant Secretary for Preparedness and Response [hereinafter "ASPR"] evaluates the request to see if it can be completely, partially, or not fulfilled.[719] SNS may be deployed in incidents of varying scope and size, at the request of state, local, tribal, and territorial [hereinafter "SLTT"] health jurisdictions, or may be prepositioned for events of national security significance at the discretion of the HHS Secretary.

However, the SNS was not created nor designed to respond to a national, or truly global emergency, like the COVID-19 pandemic. It was designed to be a stopgap for local medical

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[711] 42 U.S.C. §247d-6b.
[712] *Strategic National Stockpile*, ADMINI. FOR STRATEGIC PREPAREDNESS & RESPONSE, *available at* https://aspr.hhs.gov/SNS/Pages/default.aspx.
[713] *Id.* (The SNS was originally named the National Pharmaceutical Stockpile (NPS) and under the direction of the Centers for Disease Control and Prevention (CDC)).
[714] Todd Kuiken & Frant Gottron, CONG. RESEARCH SERV., R47400, *The Strategic National Stockpile: Overview and Issues for Congress* (updated Sept. 26, 2023) [hereinafter "The Strategic National Stockpile: Overview and Issues for Congress"].
[715] *Stockpile Response*, ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE, *available at* https://aspr.hhs.gov/SNS/Pages/Stockpile-Responses.aspx.
[716] Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188 (In response to the September 11, 2011 terrorist and anthrax attacks, Congress enacted the Public Health Security and Bioterrorism Preparedness Response Act of 2002 which formally changed the name to the SNS and expanded the role to its current capabilities.).
[717] The Strategic National Stockpile: Overview and Issues for Congress, *supra* note 714.
[718] *Strategic National Stockpile, supra* note 712.
[719] The Strategic National Stockpile: Overview and Issues for Congress, *supra* note 714.

countermeasures and biohazard events. The SNS generally maintains a broad range of medications such as antibiotics, antidotes, and antitoxins, as well as equipment and ancillary supplies such as PPE and surgical equipment.[720] There are also CHEMPACKs, Federal Medical Stations, and push packages.[721]

The Secretary of the HHS is required to:

> [M]aintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile) in such numbers, types, and amounts as are determined ... to be appropriate and practicable, taking into account other available sources, to provide for and optimize the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency and ... make necessary additions or modifications to the contents of such stockpile or stockpiles.[722]

Determining what supplies are "appropriate and practicable" is tenuous because the SNS needs to be prepared for any number of emergencies that could arise at any moment across the entire U.S. The Secretary defines "appropriate and practicable" within the context of the finite resources SNS is realistically able to provide. It would be impossible for the SNS to predict which supplies and how many would be needed for an emergency that hasn't occurred. Yet, as discussed above, there is generally a large range of items at each site.

Again, the SNS was not created to be the only source of emergency medical countermeasures in the time of a crisis. However, it is the nation's foremost supply of emergency medical countermeasures. The COVID-19 pandemic showed there were areas of weakness, particularly surrounding the states' lack of individual stockpiles.

FINDING: Dating Back to the Obama Administration, the Strategic National Stockpile Was Not Prepared for a National Public Health Emergency.

The COVID-19 pandemic placed the SNS in the eye of the storm and shook it to its core. While the SNS delivered on some aspects, the pandemic highlighted weaknesses and areas needed for improvement.

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[720] *Id.*

[721] *Id.* (CHEMPACKs are containers of nerve agent antidotes that can be used to treat exposure to a chemical incident, even with an unknown agent. More than 90 percent of the U.S. population is within one hour of a CHEMPACK location; FMS are quickly deployable caches with medical and pharmaceutical resources that can turn a pre-identified building into a temporary medical shelter during a national emergency; Push packages are prepackaged, transport-ready containers that can be delivered to an area anywhere in the U.S. within twelve hours of the decision to deploy.).

[722] 42 U.S.C. §247d-6b.

One such area is the content review process for the SNS. The HHS Secretary is required to annually review the contents of the stockpile to confirm it is relevant to current threats in public health security.[723] To aid in this review, the Secretary works "in consultation with the Public Health Emergency Medical Countermeasure Enterprise [hereinafter "PHEMCE"]."[724] The PHEMCE is an interagency group that identifies public health security needs and makes recommendations to the Secretary regarding "research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization" of medical countermeasures, including the contents and use of the SNS."[725]

The SNS is in the unique and precarious position of maintaining a large national stockpile for multiple low-probability, but high-consequence, threats while also managing the ability to rapidly respond to novel threats and other emergencies. The stockpile is equipped with enough smallpox vaccines for a national emergency, but going into the COVID-19 pandemic, the SNS was not adequately stocked with some essential assets.[726]

In 2009 the SNS responded to the H1N1 influenza outbreak and depleted its resources of PPE.[727] Even knowing a resource such as PPE will always be relevant and valuable to any type of emergency, the Obama Administration repeatedly prioritized replenishing the stockpile with other resources. During the COVID-19 crisis, ASPR and DOD awarded contracts in 2020 and 2021 to allow the SNS to significantly increase the amount of PPE and ventilators inventory.[728]

Table 3: Strategic National Stockpile (SNS) Inventory of Personal Protective Equipment (PPE) and Ventilators from December 2019 to February 2022

PPE and ventilators	Dec. 2019 inventory on hand (in millions)	Oct 2020 inventory on hand (in millions)	Feb. 2021 inventory on hand (in millions)	Feb. 2022 inventory on hand (in millions)	90-day inventory goal[a] (in millions)
Gloves	16.9	2.0	227.0	4,300.0	4,500.0
N95 respirators	12.6	107.0	307.0	626.0	300.0
Surgical or procedural masks	30.8	157.0	411.0	412.0	400.0
Gowns or coveralls	4.8	1.0	65.8	79.0	265.0
Eye protection or face shields	5.8	19.0	17.6	19.5	18.0
Ventilators	0.019	0.150	0.152	0.158	0.168

Source: Data from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services | GAO-23-106210

The SNS is the nation's largest repository of emergency medical supplies, including PPE, yet there was a national shortage of masks, PPE, and ventilators in the early days of the COVID-

[723] 42 U.S.C. §247d-6b(a)(2).
[724] *Id.*
[725] 42 U.S.C. §300hh-10a.
[726] The Strategic National Stockpile: Overview and Issues for Congress, *supra* note 714.
[727] *Id.*
[728] GAO, GAO-23-106210, PUBLIC HEALTH PREPAREDNESS: HHS SHOULD ADDRESS STRATEGIC NATIONAL STOCKPILE REQUIREMENTS AND INVENTORY RISKS (Oct. 2022).

19 pandemic. [729] In April 2020, the stores at the SNS were nearly depleted.[730] While it is vital to note the SNS is not designed to supply the entire country with supplies, starting the pandemic in the negative hindered the nation's response.

FINDING: States Must Mainatain Their Own Stockpile of Emergency Medical Supplies.

The SNS was established to ensure SLTTs had the adequate number of supplies in the face of a fast-moving emergency as a "short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient."[731] It was not established to, or even capable of, responding to a national crisis. During the COVID-19 pandemic, states overwhelmingly requested assets from the SNS at a rate the SNS could not provide.

Currently, states are not required to maintain their own stockpile of medical and ancillary equipment.[732] As every state learned during the pandemic, stockpiling ensures resources are available for a swift and efficient response without relying on the federal government. Strategic localized stockpiling can be the difference between a well-coordinated response, and a chaotic one with a potential lack of resources due to national shortages.

State-maintained stockpiles would ensure states could deploy resources at a faster timeline and have guaranteed access to assets. The SNS was not able to evenly distribute supplies across all 50 states.[733] Having the capability to be a stop-gap for multiple emergencies, does not mean the SNS was ever prepared to equip, ever jurisdiction, in every single state, at the same time.[734] A statewide stockpile would protect individuals at a much higher rate, because local leadership would be able to provide individuals with the necessary equipment immediately.[735]

Localized stockpiles would also allow states to further prepare for emergencies by tailoring the stockpiles to unique needs. The SNS is a "catch-all" program that help prepare for a broad range of problems.[736] For example, the SNS has measures against smallpox and anthrax, but not necessarily equipment to help a jurisdiction with a local disaster, such as a hurricane or earthquake, or forest fire.[737]

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[729] *Strategic National Stockpile*, *supra* note 712.
[730] Nick Miroff, *Protective gear in national stockpile is nearly depleted, DHS officials say*, THE WASH. POST (Apr. 1, 2020).
[731] *Center for the Strategic National Stockpile*, ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE, *available at* https://aspr.hhs.gov/SNS/Pages/default.aspx.
[732] The Strategic National Stockpile: Overview and Issues for Congress, *supra* note 714.
[733] *See generally*, Amy Goldstein*, et al., Desperate for medical equipment, states encounter a beleaguered national stockpile*, THE WASH. POST (Mar. 28, 2020).
[734] *Id.*
[735] *Id.*
[736] The Strategic National Stockpile: Overview and Issues for Congress, *supra* note 714.
[737] *Id.*

The state stockpile is beneficial and necessary because it would help alleviate the burden of the SNS to provide for the states, allowing the SNS to fulfill its mission statement and work to prepare and respond to emergencies to protect the health of Americans.[738]

The long-term sustainability of the SNS requires a balance of the scope and purpose of the stockpile with the provided resources. The SNS must evaluate its needs and goals with future needs and goals. The burden of this would be lifted if states established and maintained their own stockpiles to respond to emergencies.

[738] *Center for the Strategic National Stockpile*, *supra* note 731.

III. The United States' Unsecure Supply Chain Risks a Future Failed Pandemic Response

The COVID-19 pandemic profoundly impacted the global and national supply chains, particularly exposing vulnerabilities in the critical areas of medical supplies and pharmaceuticals. As the virus spread, unprecedented disruptions in the manufacturing, transportation, and distribution of supplies greatly affected how people were cared for during the pandemic.

The COVID-19 pandemic dramatically increased demand for many common consumer items and most Americans were stuck at home and turned to e-commerce for all their shopping needs.[739] This surge in demand for goods, when supplies were limited due to pandemic-related shortages and shutdowns, caused a ripple effect throughout the supply chain.[740] Ports across the world, but particularly in Southern California, grew congested to the point of inoperability.[741]

While no country was prepared for the pandemic, or its second-order effects, the vulnerability of the U.S. medical and pharmaceutical industry was unacceptable due to its significant reliance on imported finished products or resources needed to manufacture products here. COVID-19 revealed that the U.S. must make its medical and pharmaceutical supply chains more resilient, increase domestic production to curtail crippling regulations and other production roadblocks and avoid being in a position of being "cut off" by a catastrophic event, such as the COVID-19 pandemic, or geopolitical instability. This is attainable and can be fixed by ensuring U.S. companies communicate with the FDA more efficiently and establishing a system where companies are able to quickly adjust their manufacture goods.

However, there were some bright spots that, while not a dramatic change in the supply chain distribution, exhibited the American "can do" spirit and adaptability of U.S. companies in times of crisis. General Motors partnered with Ventec Life Systems and retooled its plant in Kokomo, Indiana to build ventilators for hospitals in short supply.[742] The Bacardi plant in Puerto Rico, one of the largest rum distilleries in the world, tweaked its production line to pump ethanol needed for hand sanitizer rather than distilled spirits.[743] Olein Refinery used Bacardi alcohol to make more than 1.7 million, 10-ounce bottles of hand sanitizer.[744] Burton Snowboards, a Burlington, Vermont based snowboard maker, shifted production to disposable face shields and reusable brims for health care workers.[745]

That small sample of business that were able to quickly shift gears and assist the overall U.S. supply chain are examples of what can be done to help bolster a disrupted global supply

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[739] Alicia Wallace, *Covid broke supply chains. Now on the mend, can they withstand another shock*?, CNN (Jan. 16, 2023).
[740] *Id.*
[741] Matt Egan, $*24 billion in goods is floating outside California's biggest ports*, CNN (Oct. 25, 2021).
[742] Vanessa Yurkevich & Peter Valdes-Dapena, *GM prepares to ship first round of ventilators*, CCN (Apr. 14, 2020).
[743] Jim Wyss, *Rum to the rescue? How Bacardi is tweaking production to fight the coronavirus*, MIAMI HERALD (Mar. 24, 2020).
[744] *Bacardi Helps Produce Hand Sanitizers With Change in Production*, BACARDI LIMITED (Mar. 19, 2020).
[745] Megan Cerullo, *How companies pivoted from making dresses, snowboards and whisky to face masks, gloves and sanitizer*, CBS NEWS (Mar. 10, 2021).

chain. The logistics for these companies went well, especially for how fast the turnaround was. However, a defined and ready plan of action would allow for a flawless execution of change.

FINDING: The United States Must Reduce Its Reliance on Other Countries, Particularly China, for Pharmaceuticals and Medical Supplies.

The shortage of pharmaceutical and medical supplies during the pandemic fully exposed the U.S.' dependences on China.

The medical and pharmaceutical industries are ones of particular concern for the U.S. supply chain. Many of the medications taken by Americans are manufactured overseas. But further, the active ingredients in these medications, the chemical compounds used to make them, are overwhelmingly made in China.[746] So much so that the supply has been described as China having "a global choke hold" on the chemical components of medicines distributed worldwide.[747]

The complex nature of the drug supply chain keeps consumers, hospitals, and even the FDA completely unaware of the variety of types and volumes of pharmaceutical ingredients that come from China or other foreign countries. In October 2019, before the Subcommittee on Health of the House Committee on Energy and Commerce, Dr. Woodcock testified that the FDA:

> **Dr. Janet Woodcock (October 29, 2019)**
>
> [C]annot determine with any precision the volume of [active pharmaceutical ingredients] that China is actually producing, or the volume of APIs manufactured in China that is entering the U.S. market, either directly or indirectly by incorporation into finished dosages manufactured in China or other parts of the world.[748]

In 2018, China accounted for 95 percent of U.S. imports of ibuprofen, 91 percent imports of hydrocortisone, approximately 40 percent of penicillin, and 70 percent of acetaminophen.[749]

This issue was only exasperated by the COVID-19 pandemic. During the early days of the virus, there were certain pharmacies in New York City that could not stock any brand of any simple over-the-counter painkiller, for weeks.[750]

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[746] Laurie McGinley & Carolyn Y. Johnson, *Coronavirus raises fears of U.S. drug supply disruptions*, THE WASH. POST (Feb. 26, 2020).
[747] Rosemary Gibson & Janardan Prasad Singh, China Rx: Exposing the Risks of America's Dependence on China for Medicine (Prometheus, 2018).
[748] Safeguarding Pharmaceutical Supply Chains in a Global Economy: Hearing Before Subcomm on Health, House Comm. on Energy and Commerce, 116th Cong. (Oct. 29, 2019) (statement by Dr. Janet Woodcock, Dir., Center for Drug Evaluation and Research).
[749] Doug Palmer & Finbarr Bermingham, U*.S. policymakers worry about China 'weaponizing' drug exports*, POLITICO (Dec. 20, 2019, updated Apr. 10, 2020).
[750] Chuin-Wei Yap, *Pandemic Lays Bare U.S. Reliance on China for Drugs*, THE WALL STREET JOURNAL (Aug. 5, 2020).

Another issue with the modern supply chain is that many manufacturers have suppliers and subcontractors that utilize specialized technology that can limit where products are made, or the alternative that all supplies are made in one place. One example of this is a group of chemicals known as nucleoside phosphonamidites and the additional associate reagents used to create DNA and RNA sequences.[751] All companies that develop DNA or mRNA based COVID-19 vaccines and DNA-based drug therapies rely on these reagents.[752] However, many of the key precursor materials for the vaccines and drugs are solely produced in South Korea and China.[753]

On the medical supply side, the Hubei Province in China is the global hub for producing protective-medical gear.[754] Hubei Province is where the virus first emerged in the city of Wuhan. Wuhan was almost completely locked down for many months during the early parts of the pandemic, leaving the U.S. in the tenuous position of relying on current inventories of medical supplies knowing that the primary manufacturer of those supplies may be out of commission for some time.

While undoubtedly, the dependence on China and other foreign nations in the supply chain must be addressed, there are several actions U.S. companies should adopt to help address market issues.

Dr. Marston articulated how the COVID-19 pandemic underscored how fragile and vital the supply chain is and discussed steps the FDA can take to improve the ability to provide supplies and mitigate shortages.[755] One major change that must be addressed is the lack of reporting requirement from companies to the FDA when they experience a rise in demand that they are not able to keep up with.[756] An example of this is in 2022 when a surge of influenza and respiratory viruses in children created an abnormally high demand for mainstay medicines.[757] Many parents had to go to multiple stores to find any form of pain or fever reducer.[758]

Another change, that will not only strengthen the U.S. supply chain but protect the safety and health of Americans, will be requiring drug companies to supply more detailed labels for their products. Currently, drug labels from U.S. companies are not required to identify the original manufacturer or specify reliance on different manufactures for APIs for the produced drugs.[759] Additionally, drug labels do not include the original manufacturer of limited high-risk

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[751] Willy C. Shih, *Global Supply Chains in a Post-Pandemic World*, HARVARD BUSINESS REVIEW (Sept.-Oct. 2020).
[752] *Id.*
[753] *Id.*
[754] Melanie Evans & Drew Hinshaw, *Masks Run Short as Coronavirus Spreads*, THE WALL STREET JOURNAL (Feb. 27, 2020).
[755] Preparing for the Next Pandemic, *supra* note 230 (Statement or Dr. Marston, Chief Medical Dir., U.S. Food and Drug Admin.).
[756] *Id.*
[757] Brenda Goodman & Raenu Charles, *Meds for kids with pain and fever are in high demand. Here's what to do if you can't find them*, CNN (Dec. 9, 2022).
[758] *Id.*
[759] Preparing for the Next Pandemic, *supra* note 230 (Statement or Dr. Marston, Chief Medical Dir., U.S. Food and Drug Admin.).

excipients, along with API and finished drug product. Providing this information could help mitigate supply impacts, enhance national security, and improve public health preparedness.[760]

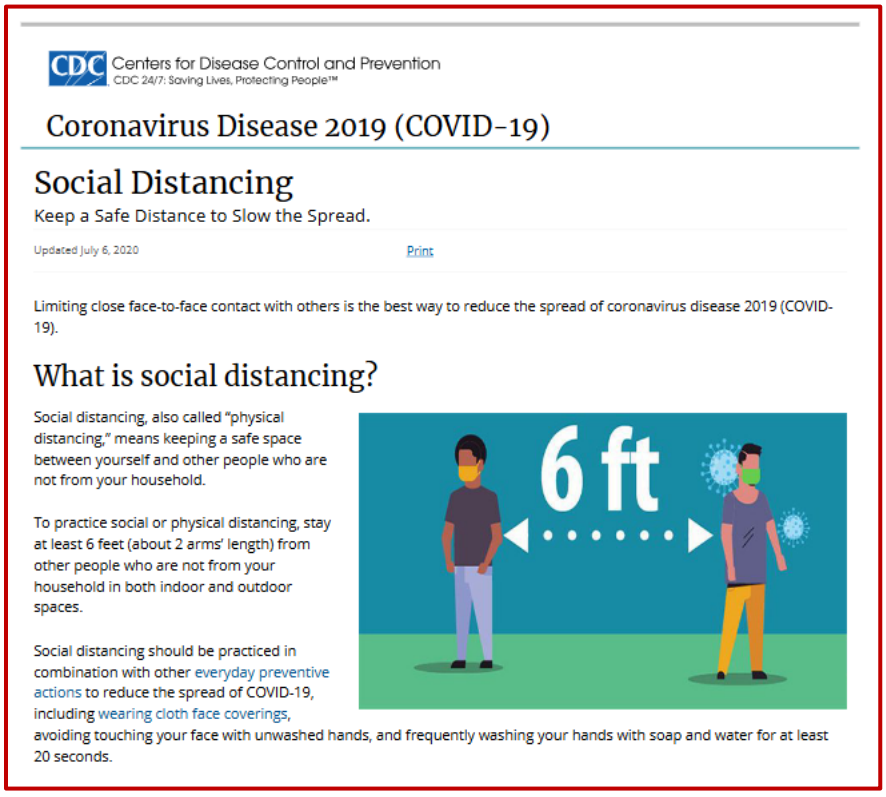
Finally, Dr. Marston, testified that medical-device manufacturers are not required to alert the FDA about a supply chain disruption outside of a public-health emergency.[761] She used the painful, real-life example of a tornado taking out a factory.[762] She stated that the FDA might know about it and see it on the news and call the manufacturers itself, but the manufacturer does not have to alert the FDA that there may be a disruption in the supply chain because of an event outside of a public health emergency.[763]

The U.S.'s current dependence on China for medicine and medical supplies is a serious national security risk. This over-reliance could easily be weaponized against us. The supply chain vulnerability was not a new problem, but one that was laid bare during the COVID-19 pandemic.

[760] Mary Van Beusekom, *Report details where top 100 brand-name Rx drugs are made*, CIDRAP NEWS (Jan. 26, 2022).
[761] [761] Preparing for the Next Pandemic, *supra* note 230 (Statement or Dr. Marston, Chief Medical Dir., U.S. Food and Drug Admin.).
[762] *Id.*
[763] *Id.*

IV. The Six-Foot Social Distancing Requirement Was Not Supported by Science

Social distancing was one of the most consequential policies of the COVID-19 pandemic. Social distancing is the practice of intentionally maintaining a physical space between yourself and other people. On March 22, 2020, the CDC issued guidance specifically designating six feet, or two arm's length, as the distance that would best reduce the spread of the coronavirus.[764]



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Coronavirus Disease 2019 (COVID-19)

Social Distancing

Keep a Safe Distance to Slow the Spread.

Updated July 6, 2020 Print

Limiting close face-to-face contact with others is the best way to reduce the spread of coronavirus disease 2019 (COVID-19).

What is social distancing?

Social distancing, also called "physical distancing," means keeping a safe space between yourself and other people who are not from your household.

To practice social or physical distancing, stay at least 6 feet (about 2 arms' length) from other people who are not from your household in both indoor and outdoor spaces.

Social distancing should be practiced in combination with other everyday preventive actions to reduce the spread of COVID-19, including wearing cloth face coverings, avoiding touching your face with unwashed hands, and frequently washing your hands with soap and water for at least 20 seconds.

Governments at every level and private entities implemented social distancing nationwide in manner that adversely impacted nearly every person in the country. Small businesses limited the capacity of patrons allowed in the shop at one time, grocery stores placed stickers on the floor alerting people where to stand, and schools struggled to reopen because the rule limited the number of desks that could be in a classroom at one time.

FINDING: There Was No Quantitative Scientific Support for Six Feet of Social Distancing.

Six feet of social distancing was a phrase and rule known by every single American during the pandemic. Amazingly, social distancing guidance was not revised until August 2022.[765] Even though it was CDC guidance and not a mandate, it was forcefully implemented by

[764] *Social distancing: keep a safe distance to slow the spread*, U.S. CTR. FOR DISEASE CONTROL AND PREVENTION (July 6, 2020).
[765] Dan Diamond, *In the pandemic, we were told to keep 6 feet apart. There's no science to support that*, THE WASH. POST (June 2, 2024).

state and local governments and caused lots of strife amongst Americans.[766] Social distancing requirements were largely responsible for closing businesses, heightening a sense in loss of community, and were part of the reasoning schools could not reopen for so long.[767]

While six feet of social distancing was a cornerstone policy associated with the COVID-19 pandemic, like many others that were implemented, public health leadership did not articulate or explain the science behind the decision.

Dr. Fauci testified regarding what studies he, and the CDC, reviewed before imposing such a harsh policy on the American people, for such a length of time.

Dr. Anthony Fauci (January 9, 2023)

Q. Do you recall when discussions regarding, kind of, the at least a 6 foot threshold began?

A. The 6 foot in the school?

Q. Six foot overall. I mean, 6 foot was applied at businesses…it was applied in schools, it was applied here. At least how the messaging was applied was that 6-foot distancing was the distance that needed to be --

A. You know, I don't recall. It sort of just appeared. I don't recall, like, a discussion of whether it should be 5 or 6 or whatever. It was just that 6 foot is

Q. Did you see any studies that supported 6 feet?

A. I was not aware of studies that, in fact, that would be a very difficult study to do.

Q. I know. I'm just trying to figure out why 6 versus 3 or 4 or 5.

A. Yeah. Yeah…I think it would fall under the category of empiric. Just an empiric decision that wasn't based on data or even data that could be accomplished. But I'm thinking hard as I'm talking to you.

Q. Uh huh.

A. I don't recall, like, a discussion of, "Now it's going to be" it sort of just appeared, that 6 feet is going to be the distance.[768]

[766] Kevin Sikali, *The dangers of social distancing: How COVID-19 can reshape our social experience,* JOURNAL OF COMMUNITY PSYCHOLOGY (Aug. 16, 2020).
[767] *Id.*
[768] Fauci TI 2, *supra* note 81, at 183-184.

Dr. Collins testified:

Dr. Francis Collins (January 11, 2023)

Q. …We asked Dr. Fauci where the six feet came from and he said it kind of just appeared, is the quote. Do you recall science or evidence that supported the six-foot distance?

A. I do not.

Q. Is that I do not recall or I do not see any evidence supporting six feet?

A. I did not see evidence, but I'm not sure I would have been shown evidence at that point.

Q. Okay.

A. I was not involved in that conversation.

Q. Since then, it has been an awfully large topic. Have you seen any evidence since then supporting six feet?

A. No.[769]

In June 2024, at a public hearing, Dr. Fauci continued to articulate that the six-foot rule for social distancing was not supported by quality scientific standards. He additionally attempted to further distance himself from the issue by stating the decision making of this policy implementation was the responsibility of the CDC.

Dr. Anthony Fauci (June 3, 2024)

You know, one I'm sure is going to come up later is the issue of the six foot distance, and I made the statement that it ''just appeared.'' And that got taken like, ''I don't know what's going on. It just appeared.'' It actually came from the CDC. The CDC was responsible for those kinds of guidelines to schools, not me. So, when I said that it just appeared, it appeared. Was there any science behind it? What I meant by ''no science behind it'' is that there wasn't a controlled trial that said, compare 6-foot with 3 feet with 10 feet. So there wasn't that scientific evaluation of it.[770]

[769] Collins TI, *supra* note 219, at 225-226.
[770] Fauci Hearing, *supra* note 231, at 24.

At the hearing, Dr. Fauci discussed that he did not want to appear to push back against another scientific institution. He again placed the blame on the CDC, even though he noted the CDC was part of the COVID-19 response team.

Dr. Anthony Fauci (June 3, 2024)

Q. Dr. Fauci, one of the controversial regulations of the pandemic was the six-foot distancing rule. This rule became an important policy consideration in subsequent regulations. However, you testified recently, and I'm quoting, this six-foot rule "sort of just appeared." Do you think that a rule that "sort of just appeared" is substantial justification for the regulations that we saw based on that six-foot rule?

A …When saying it "just appeared," it came from the CDC——

Q. …What was your relationship with the CDC when you saw a regulation which was not based in the current science?

A. Well, when I say it was not based in science, I meant a prospective clinical trial to determine whether 6-foot was better than 3, was better than 10. What——

Q. But once we realized that the virus was not spread by droplets and was aerosolized, did you feel an indication to go back to the CDC and say, let's base this on science, let's get rid of this six-foot rule? This six-foot rule crippled businesses… It allowed students to stay at home and not learn. Americans suffered. And that suffering continues, because the fracture of trust in American scientists continues to this day. Did you not feel an obligation, for something that just sort of appeared, not to go back to the CDC and say, let's base this on what we know?

A. It was a CDC decision, and it was clear——

Q. Were you in communication with the CDC?

A. CDC was part of the coronavirus response team, yes.

Q. And you didn't feel an obligation to go to them and say, look, Americans aren't going to trust——

A. Yes.

Q. [continuing]. Us, we're providing them with misinformation?

A. We had discussions at the White House about that. We did. But the CDC's decision—and it was their decision to make, and they made it. at the NIH, to challenge that? I've challenged the CDC multiple times——

…

Q. Publicly you challenged them on this six-foot distancing rule?

A. It is not appropriate to be publicly challenging a sister organization.[771]

Even though Dr. Fauci was arguably one of the most notable, recognizable faces and names of the COVID-19 response team, and a strong advocate for the six-foot of separation rule, he continuously stated the policy was blindly accepted, without any further discussion as to possible consequences or alternative routes.

Dr. Anthony Fauci (June 3, 2024)

Q. Do you recall if it was ever suggested to be 10 feet?

A. You know, I don't recall if it was ever suggested it was 10 feet. But when I made my explanation of what it 6 versus 3 versus not even worrying about it at all.

Q And you said today that there were discussions at the White House about the six-foot rule. You don't recall if it was discussions about whether or not it should be 3 or should be 10 or should be 6?

A. You know, I don't recall what the exact discussion was. But as I've said in response to multiple questions, what we had was it came to CDC was said that on the basis of their evaluation, which was based on the droplet approach, that six-foot would be the go. And since there was no clinical trials going one way or the other, that's why it was accepted by the group.[772]

The justification for one of the most impactful COVID-19 policies, that arguable affected the most Americans in their day-to-day lives, was "it sort of just appeared." There were no scientific trials or studies conducted before this policy was implemented, there appeared to be no pushback or internal discussion amongst the highest level of leadership, and more importantly there appears to be no acceptance of responsibility. That is an unacceptable answer from public health leadership. Decisions of this magnitude must have scientific backing that can be explained to the American public.

[771] Fauci Hearing, *supra* note 231, at 36-37.
[772] Fauci Hearing, *supra* note 231, at 58-59.

V. Masks and Mask Mandates Were Ineffective at Controlling the Spread of COVID-19.

Much of the conversations around the earliest days of the COVID-19 pandemic surrounded inconsistent messaging and a lack of understanding around the virus in general. One area of policy that was riddled with contradictions was the use of face masks. Throughout the pandemic federal, state, and local governments had conflicting policies and rhetoric regarding wearing face masks.

In the very early days, public health officials urged the general public not to wear masks.[773] That messaging was then replaced saying individuals should wear a mask, and then the American people were told they must wear a mask.[774] The first recommendation for the public to wear face masks by the CDC was April 3, 2020.[775] But before this, the WHO and CDC reported healthy members of the public at large should not wear masks, reserving them for those who were sick or most susceptible to the virus.[776] On February 29, 2020, the U.S. Surgeon General tweeted, urging people not to buy masks and stated proper hygiene and a flu vaccine would be an adequate solution to the virus.[777]

During a *60 Minutes* interview on March 8, 2020, Dr. Fauci similarly stated "when you're in the middle of an outbreak, wearing a mask might make people feel a little bit better and it might even block a droplet, but it's not providing the perfect protection that people think that it is."[778] This was consistent with the CDC and WHO's guidance, which in late March 2020 recommended using masks if one was sick or caring for a sick individual.[779]

But these sentiments were reversed just about a month later. On April 3, 2020, the CDC issued guidance recommending non-medical face coverings be worn in areas with high amounts of potential community transmission.[780] The guidance stated to wear "cloth face coverings fashioned from household items or made at home from common materials ... as an additional, voluntary public health measure."[781] The CDC went as far as posting a video teaching the public how to make masks with a T-shirt and rubber bands.

These initial changes in statements and reversals of policy are understandable, as they were said in the panicked early days of the novel coronavirus, and public health officials were

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[773] Holly Yan, *Want to prevent another shutdown, save 33,000 lives and protect yourself? Wear a face mask, doctors say*, CNN (June 29, 2020).
[774] *Id.*
[775] Chris Megerian, *et al., CDC recommends wearing face masks during coronavirus pandemic*, LOS ANGELES TIMES (Apr. 3, 2020); Colin Dwyer & Allison Aubrey*, CDC Now Recommends Americans Consider Wearing Cloth Face Coverings In Public*, NPR (Apr. 3, 2020).
[776] Holly Yan, *supra* note 773.
[777] This tweet has since been deleted.
[778] 60 Minutes, CBS (Mar. 8, 2020).
[779] *See generally*, Holly Yan, *supra* note 773.
[780] Chris Megerian*, supra* note 775; Colin Dwyer & Allison Aubrey*, supra* note 775.
[781] RECOMMENDATIONS REGARDING THE USE OF CLOTH FACE COVERINGS, ESPECIALLY IN AREAS OF SIGNIFICANT COMMUNITY-BASED TRANSMISSION, CTRS. FOR DISEASE CONTROL AND PREVENTION (Apr. 3, 2020) *available at* https://stacks.cdc.gov/view/cdc/86440.

working with the limited information they had on hand. However, public health officials eventually acquired more information about COVID-19 at a rapid pace.

Ultimately, a systematic review carried out by Cochrane Collaboration—one of the most highly regarded methodologies in evidence-based healthcare—found that the pooled randomized control trials they analyzed "did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks" and that "[t]here were no clear differences between the use of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection."[782] These results appear to directly contradict public health agencies' and local governments' support for broadly requiring masking throughout much of the pandemic.

FINDING:	Public Health Officials Flip Flopping on the Efficacy and Use of Face Masks Without Full Scientific Transparency Caused Mistrust in Public Health Establishments.

On January 20, 2021, in one of his very first actions as President, President Biden signed Executive Order (EO) 13991. Part of the order reads:

> The heads of executive departments and agencies (agencies) shall immediately take action, as appropriate and consistent with applicable law, to require compliance with CDC guidelines with respect to wearing masks, maintaining physical distance, and other public health measures by: on-duty or on-site Federal employees; on-site Federal contractors; and all persons in Federal buildings or on Federal lands.[783]

President Biden signed another EO, the very next day, compelling the Transportation Security Administration and other federal agencies to also require face masks on all forms of domestic and international travel.[784] This language in essence made CDC guidances actionable. Before, these guidances were non-binding recommendations provided by the public health officials as a best practice; however, President Biden's EO called for these actions to be mandatory.

Approximately four months later, the Biden Administration and the CDC amended the guidelines on mask wearing. On April 27, 2021, it was announced that fully vaccinated individuals did not need masks during small outdoor gatherings, but that they should still be worn at large outdoor gatherings as well as indoor events.[785]

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[782] Tom Jefferson, *et al., Physical interventions to interrupt or reduce the spread of respiratory viruses*, COCHRANE (Jan. 30, 2023).
[783] Exec. Order No. 13991, 86 FR 7045 (Jan. 25, 2021).
[784] Exec. Order No. 13998. 86 FR 7205 (Jan. 21, 2021).
[785] Jason Hoffman & Maegan Vazquez, *Biden pushes new CDC mask guidance as a reason why all Americans should get vaccinated*, CNN (Apr. 27, 2021); Elizabeth Cohen, *et al., CDC issues new outdoor mask guidance for fully vaccinated people*, CNN (Apr. 27, 2021).

On May 13, 2021, the CDC announced that the mask mandate was effectively lifted and individuals who were fully vaccinated did not need to wear masks at all (except as otherwise required, such as the mandate on public transportation which was still in effect).[786]

This abrupt announcement and change caused mass confusion amongst state and local officials, as well as the public at large. People did not know which way to turn or which policy to follow.[787] Senior government officials did not alleviate the confusion. Merely two days before the CDC dropped the guidance on required face masks, Dr. Walensky appeared before Senate HELP and adamantly defended the guidance at the time. At the hearing, Dr. Walensky stated the measures that are known to prevent the spread of the virus must remain the policy, despite calls from lawmakers that suggested the CDC was too harsh in requesting masks for outdoors.[788] This abrupt announcement stunned medical and public health experts. At the Senate hearing, Dr. Walensky doggedly argued the CDC policy was the most appropriate at the time, yet two days later it was changed without providing people proper notice to prepare for the lifting of the restriction.

Due to the change in Biden Administration policy and CDC guidance, many states began lifting their mask mandates.[789] On May 20, 2021, in yet another whiplash moment, Dr. Fauci stated he believed Americans were "misinterpreting" the guidance.[790] In an interview, he stated "[the CDC] said: If you are vaccinated, you can feel safe — that you will not get infected either outdoors or indoors. It did not explicitly say that unvaccinated people should abandon their masks."[791] This is one of many statements that were provided by public health leadership without the backing of a scientific study. It was a declaration by Dr. Fauci, verified by Dr. Fauci.

On July 26, 2021, the CDC issued yet another change in guidance, stating even vaccinated individuals should wear masks when indoors, if in a region with a substantial and high transmission.[792] The guidance also recommended masks be mandated at schools for all students and faculty, regardless of vaccination status. The Biden Administration and CDC provided no scientific justification or information for the change, apart from citing the new Delta variant.[793]

Citing the availability of vaccines, treatments, and improved testing options, on February 25, 2022, the CDC stated residents in areas of substantial and high transmissions (of which 70 percent of the country was no longer considered due to a change in the CDC metrics when determining COVID-19 risk by county) did not need to wear a mask, regardless of vaccination

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[786] Paul LeBlanc & Kaitlan Collins, *Biden touts new CDC mask guidance as 'a great day for America'*, CNN (May 13, 2021).
[787] *Id.*
[788] An Update from Federal Officials on Efforts to Combat COVID-19: Hearing before Senate Committee on Health, Education, Labor & Pensions, 117th Cong., (May 11, 2021).
[789] Chas Banner, *Mask Mandates Are Back – Even for the Vaccinated. Here's What to Know*, N.Y. MAGAZINE (Aug. 7, 2021).
[790] *See,* Wilson Wong, *Fauci says public is 'misinterpreting' latest CDC mask guidance*, NBC (May 20, 2021).
[791] *Id.*
[792] HOW TO PROTECT YOURSELF & OTHERS, CTRS. FOR DISEASE CONTROL AND PREVENTION (updated July 26, 2021) (archived copy with Select Subcomm. Staff).
[793] *Id.*

status.[794] By April 2022, mask mandates were lifted in all U.S. states, except Hawaii that still had a mask mandate in schools.[795]

In times of national public health crisis, Americans should be able to turn to the CDC to guide us through turmoil. Yet, during the COVID-19 pandemic, the worst public health crisis in our modern era, the CDC constantly redirected their opinions and provided conflicting answers. These actions undermined the American people's belief in the CDC, public health leadership, and science as a whole. At the start of the pandemic, 69 percent of Americans believed what the CDC said, yet by March 2022 that number was only 44 percent.[796] This must change before a future pandemic.

FINDING: The Biden Administration Exceeded its Authority by Mandating Masks.

In February 2021, the CDC, under President Biden's EO, required the use of masks on public transportation under section 264(a) of the Public Health Service Act of 1944 [hereinafter "PHSA"].[797] On April 13, 2022, the CDC announced it extended the requirement for face masks on public transportation by an additional 15 days.[798] However, a lawsuit filed by 21 state Attorneys General called to block the federal mandate extension, particularly after the CDC suggested in a guidance in late February 2022 that almost 70 percent of Americans could stop wearing masks.[799]

On April 18, 2022, a federal judge of the District Court for the Middle District of Florida, found the mandate unlawful, stating the CDC exceeded its legal authority.[800] The PHSA allows the CDC to prevent the interstate spread of communicable disease.[801] The CDC argued the mask requirement, which was issued as an emergency action, was "reasonable and necessary measure to prevent the introduction, transmission, and spread of COVID-19" and that it was acting within the scope of power granted by Congress under the PHSA.[802]

The court held the CDC's interpretation of its powers granted by Congress was overly broad and struck down the mandate as unlawful.[803] The court noted that while section 264(a) of the PHSA does allow for regulations to curb the spread of communicable diseases, the power to do so must be done within the enumerated actions of the regulation, namely "inspection,

[794] Berkeley Lovelace Jr. & Erika Edwards, *Indoor mask use no longer necessary across most of the U.S., CDC says*, NBC (Feb. 25, 2022).
[795] Katie Teague, *et al., Where Are COVID-19 Mask Mandates Still in Effect*?, CNET (Apr. 13, 2022).
[796] James Hamblin, *Can Public Health Be Saved?,* THE N.Y. TIMES (Mar. 12, 2022).
[797] *Health Freedom Defense Fund, Inc. v. Joseph R. Biden*, No. 8:21-cv-01693-KKM-AEP, 2022 (M.D. Fla. Apr. 18, 2022).
[798] Will Stone & Pien Huang, *CDC extends transportation mask mandate until May 3,* NPR (Apr. 13, 2022).
[799] Apoorva Mandavilli, *New C.D.C. Guidelines Suggest 70 Percent of Americans Can Stop Wearing Masks*, THE N.Y. TIMES (Feb. 25, 2022).
[800] *Health Freedom Defense Fund, Inc. v. Joseph R. Biden*.
[801] *Id.*
[802] *Id.*
[803] *Id.*

fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles, and other measures."[804]

The CDC argued that "sanitation" measures were intended for the general promotion of hygiene and prevention of disease, and as such the mask mandate was appropriate under that definition, even though "sanitation" is not defined by the PHSA.[805] The court ruled masking was distinct from sanitation.[806] The court also discussed that since its enaction, the PHSA has rarely been invoked, and "generally limited to quarantining infected individuals and prohibiting the import or sale of animals known to transmit disease."[807] The decision further noted the CDC's use of section 264(a) (notably, shutting down the cruise ship industry and stopping landlords from evicting tenants who had not paid their rent) were ruled as acts that also exceeded the CDC's statutory authority.[808]

The court's decision also discussed how the CDC did not adequately follow the rules of the Administrative Procedure Act [hereinafter "APA"] by not providing the public with an adequate review and comment period and further not properly explaining its reasoning.[809] Ultimately, the court ruled the mask mandate exceeded the CDC's, and by extension the Biden Administration's, statutory authority and violated the procedures for agency rulemaking under the APA.[810] This decision almost immediately ended the mask mandate for public transportation. The judge presiding over the case wrote in her opinion, "[i]f Congress intended this definition, the power bestowed on the C.D.C. would be breathtaking…And it certainly would not be limited to modest measures of 'sanitation' like masks."[811]

FINDING:	The U.S. Centers for Disease Control and Prevention Relied on Flawed Studies to Support the Issuance of Mask Mandates.

In issuing guidances that mandated the use of masks across the country, the CDC publicly relied on several different studies to justify the actions. The CDC provided a list of approximately 15 studies that demonstrated wearing masks reduced new infections.[812] Yet, all 15 of the provided studies are observational studies that were conducted after COVID-19 began and, importantly, none of them were RCTs.[813] RCTs are considered the gold standard in medical research.

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[804] *Id.*
[805] *Id.*
[806] *Id.*
[807] *Id.*
[808] *Id.*
[809] *Id.*
[810] *Id.*
[811] *Id.*
[812] Science Brief: *Community Use of Masks to Control the Spread of SARS-CoV-2*, CTRS. FOR DISEASE CONTROL AND PREVENTION (last updated Dec. 6, 2021).
[813] *Id.*

One study the CDC utilized to mandate masks was the "Missouri hairstylists."[814] There, an observational cohort study, focused on two hairstylists that were positive for COVID-19 while providing hair styling services to customers.[815] The stylists worked on 139 customers over several days, and both stylists were masked the whole time. Many of the customers were as well, but not all of them were. Out of 139 people, 67 customers chose to test for COVID-19 after receiving their service, and all of whom tested negative. The other 72 either did not test for COVID-19 or did not report any symptoms of the virus.

While these numbers appear significant, this study is far from perfect. For example, the 72 clients who reported no COVID-19 symptoms could absolutely have been positive but asymptomatic, or purposely chose not to report to the Green County Health Department.[816] There was also no control group for this study. There was no way to know, how many people, if anyone at all, could have been infected had neither stylist worn a mask during the appointments. Further, the study does not discuss any alternatives as to why no one became sick. There was no discussion of the ventilation of the salon, the hand hygiene of the stylists, or the fact that a client and stylists generally do not come face to face.

The CDC also utilized a study of 1,000 public school children in Arizona that concluded students without mask mandates were 3.5 times as likely to experience COVID-19 outbreaks as the ones that did have mask mandates.[817] The study published in September 2021 reviewed school-associated COVID-19 outbreaks and compared rates across schools with and without mandates.[818]

However, this study also posed serious flaws. The very first lines of the paper note the authors studied school mask policies and COVID-19 outbreaks between "July 15-August 31, 2021."[819] This time frame is important, because the schools that were reviewed for the study were not all open at the same time. For example, some of these schools were not open during the month of July at all; some of the other schools did not have a start date until August 10; and some of the schools only had a few weeks of student activity during the summer.[820] There was also not a control for the vaccination status of staff and students and the definition of an outbreak of COVID-19 was two or more cases among staff or students within a 14-day period versus cases per week per student.[821] Further, the list of Maricopa County schools used for the study included: at least three schools from Pima County (two hours away), one preschool, at least one virtual academy, and more than 80 vocational programs.[822] When asked about these discrepancies, the

[814] M. Joshua Hendrix, *et al., Absence of Apparent Transmission of SARS-CoV-2 from Two Stylists After Exposure at a Hair Salon with a Universal Face Covering Policy — Springfield, Missouri, May 2020*, MMWR (July 17, 2020).
[815] *Id.*
[816] Jeffrey H. Anderson, *Do Masks Work?*, CITY JOURNAL (Aug. 11, 2021).
[817] Megan Jegn, *et al., Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks — Maricopa and Pima Counties, Arizona, July–August 2021*, MMWR (Sep. 24, 2021).
[818] *Id.*
[819] *Id.*
[820] *Id.*
[821] *Id.*
[822] *Id.*

journal replied "*MMWR* is committed to quickly correcting errors when they are identified. We reviewed the specific items that you describe below and found no errors."[823]

A similar study out of Georgia was published in May 2021.[824] In this study, authors reviewed case rates of 90,000 students, comparing schools with and without mandates.[825] It showed 37 percent lower instances of COVID-19 in schools where staff were required to wear a mask and 21 percent lower for children.[826] However, the authors noted the difference was not statistically significant, and thus the data could not be used to infer causal relationships.[827]

Yet, in an interview with *Face the Nation*, at a White House briefing, and a public tweet, the CDC cited the Arizona study and claimed in a blanket statement that lack of school mask mandates more than tripled the risk of outbreaks.[828]

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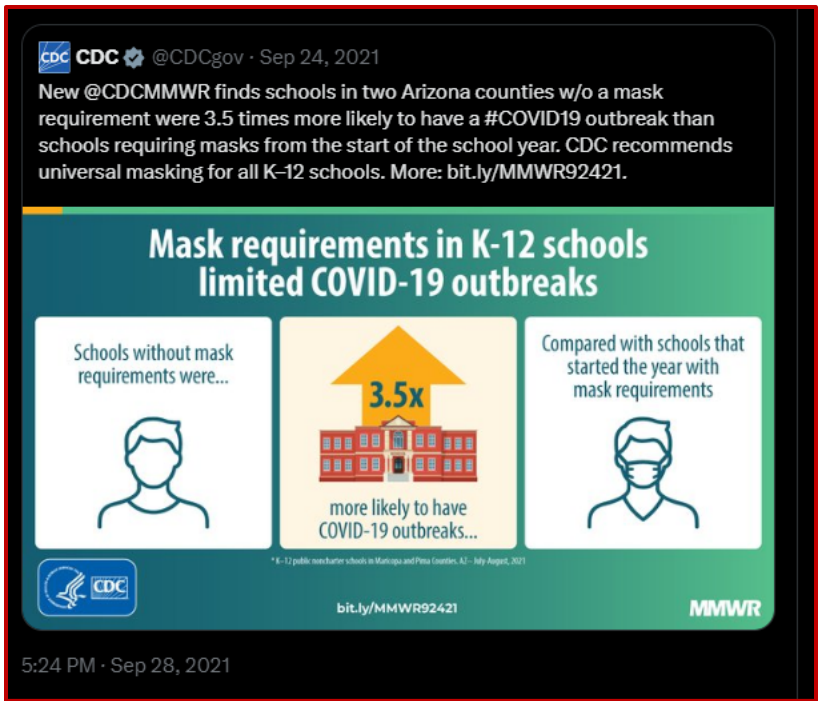
[823] David Zweig, *The CDC's Flawed Case for Wearing Masks in School*, THE ATLANTIC (Dec. 6, 2021).
[824] Jenna Gettings, *et al., Mask Use and Ventilation Improvements to Reduce COVID-19 Incidence in Elementary Schools — Georgia, November 16–December 11, 2020*, MMWR (May 28, 2021).
[825] *Id.*
[826] *Id.*
[827] *Id.*
[828] David Zweig, *The CDC's Flawed Case for Wearing Masks in School*, THE ATLANTIC (Dec. 6, 2021).


CDC @CDCgov · Sep 24, 2021
New @CDCMMWR finds schools in two Arizona counties w/o a mask requirement were 3.5 times more likely to have a #COVID19 outbreak than schools requiring masks from the start of the school year. CDC recommends universal masking for all K–12 schools. More: bit.ly/MMWR92421.
Mask requirements in K-12 schools limited COVID-19 outbreaks
Schools without mask requirements were...
3.5x
more likely to have COVID-19 outbreaks...
Compared with schools that started the year with mask requirements
bit.ly/MMWR92421
MMWR
5:24 PM · Sep 28, 2021

Additional, peer-reviewed, literature on masking began to emerge as the pandemic progressed. In May 2020, a study published in *Emerging Infectious Diseases* found "[i]n pooled analysis, we found no significant reduction in influenza transmission with the use of face masks."[829] There, researchers conducted a professional literature review of several RCTs surrounding different nonpharmaceutical interventions for pandemic influenza studies, including ten on face masks.[830] Also in May 2020, the *New England Journal of Medicine* published an article on masking in hospitals.[831] Those researches observed, "[w]e know that wearing a mask outside health care facilities offers little, if any, protection from infection."[832] A November 2022 *British Medical Journal* study found that masking of Spanish school-aged children with cloth masks did not lower SARS-CoV-2 transmission, "suggesting that this intervention was not effective."[833]

During a deposition related to the lawsuit filed by the Attorneys General of Louisiana and Missouri, which alleges collusion by the Biden Administration to censor COVID-19 speech on social media, counsel for the plaintiff asked Dr. Fauci which studies the CDC relied upon to justify the mask mandates.[834] They asked Dr. Fauci how many studies, and if any placebo-based

[829] Jingyi Xiao, *et al., Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures,* EMERGING INFECTIOUS DISEASES (May 26, 2020).
[830] EMERGING INFECTIOUS DISEASES (May 26, 2020).
[831] Michael Klompas, M.D., M.P.H., *et al., Universal Masking in Hospitals in the Covid-19 Era*, THE NEW ENGLAND JOURNAL OF MEDICINE (Apr. 1, 2020).
[832] *Id.*
[833] Ermengol Coma, *et al., Unravelling the role of the mandatory use of face covering masks for the control of SARS-CoV-2 in schools: a quasi-experimental study nested in a population-based cohort in Catalonia (Spain),* BRITISH JOURNAL OF MEDICINE (Nov. 3, 2022).
[834] *Missouri v. Biden*, 3:22-cv-01213, (W.D. La. Jan. 11, 2023) (Deposition of Dr. Anthony Fauci (Nov. 23, 2022)).

randomized, double-blind studies were conducted between February 2020 and April 2020.[835] Dr. Fauci answered that he could not recall.[836] It is absolutely essential that these decisions—decisions that had real life consequences—can be verified after the fact.[837]

Dr. Fauci admitted that at the population level, masks do not provide effective coverage, stating, "[f]rom a broad public-health standpoint, at the population level, masks work at the margins — maybe 10 percent."[838] He does go on to say that for an individual, who religiously wears a mask, the highest standard of a well-fitted KN95 or N95 is effective.[839] However, the reality of that perfect storm of factors coming together for one person, let alone the entire country, is impossible.

In late January 2023, the most rigorous and comprehensive review of the scientific literature on masks during the COVID-19 pandemic was published by Cochrane.[840] Cochrane is considered the worlds most respected organization for evaluating health interventions, is known for being the single best resource for methodologic research,[841] and is recognized as having the highest standard of evidence-based healthcare.[842]

The January 2023 publication found that wearing any kind of face covering "probably makes little or no difference" in reducing the spread of respiratory illness.[843] The study reviewed 15 trials comparing outcomes of wearing surgical masks versus no mask and also versus N95 masks, in hospital and community settings during the pandemic. The conclusion was that the value of wearing masks was approximately zero.[844] "There is just no evidence that they make any difference. Full stop."[845]

The trajectories of the rate of COVID-19 infections for states with mask mandates and states without is virtually identical. Eleven states never mandated masks, while the rest had some form of enforcement.[846] Mandates generally began in early 2020 and stayed until summer of 2021, some into 2022.[847]

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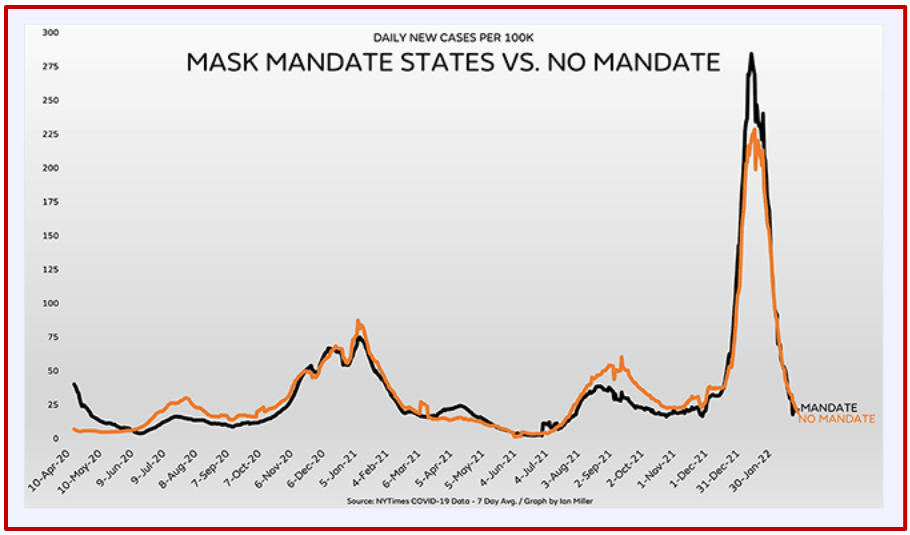
[835] *Id.*
[836] *Id.*
[837] *Id.*
[838] David Wallace-Wells, *Dr. Fauci Looks Back: 'Something Clearly Went Wrong'*, THE N.Y. TIMES (Apr. 24, 2023).
[839] *Id.*
[840] Tom Jefferson, *et al., Physical interventions to interrupt or reduce the spread of respiratory viruses*, COCHRANE (Jan. 30, 2023).
[841] Jeremy Grimshaw, *So what has the Cochrane Collaboration ever done for us? A report card on the first 10 years*, CMAJ (Sep. 28, 2004).
[842] A. Cipriani*, et al., What is a Cochrane review?*, EPIDEMIOLOGY AND PSYCHIATRIC SCIENCES (Sep. 20, 2011).
[843] Tom Jefferson*, et al., Physical interventions to interrupt or reduce the spread of respiratory viruses*, COCHRANE (Jan. 30, 2023).
[844] Scott Atlas, Steve Hanke, Philip Kerpen, & Casey Mulligan, *COVID Lessons Learned: A Retrospective After Four Years,* COMM. TO UNLEASH PROSPERITY (Mar. 2024).
[845] A. Cipriani, *et al., What is a Cochrane review?,* EPIDEMIOLOGY AND PSYCHIATRIC SCIENCES (Sep. 20, 2011).
[846] Ian Miller, Unmasked (Post Hill Press, 2022).
[847] *Id.*



It is apparent that the CDC and the Biden Administration cherry-picked observational data to fit their narrative that masks are fully effective. Yet, that is not the role of the CDC. The CDC is an agency meant to protect the American people, and part of that responsibility includes conducting, sponsoring, or at the very least examining clinical trials to actually have the best available research before formulating its guidance.

FINDING:	Forcibly Masking Young Children, Ages Two and Older, Caused More Harm than Good.

One area where the mask mandate may have caused quantifiable harm is the masking of children. The April 3, 2020-February 25, 2022 (with a brief lift between May 13,2021-July 27, 2021) CDC guidance masking in schools was unbelievably far reaching. It called for "universal indoor masking by all students (age two and older), staff, teachers, and visitors to K-12 schools, regardless of vaccinations status."[848]

Many countries, including the U.K., Sweden, Norway, and Denmark, followed the guidelines of the WHO. The WHO specifically did not recommend masking children aged five or younger because they are at low risk of illness, masks are "not in the overall interest of the child," and also because most children that age are not capable of wearing a mask properly or efficiently.[849] The WHO also recommended children aged six through 11 not routinely wear masks because of potential adverse impact to psychosocial and learning development.[850] The WHO further explicitly advised against children wearing masks during physical activities, such as outside playground time, so as not to impede their breathing.[851]

But beyond those logical reasons as to not require young children to wear a mask all day, every day, are additional, still unknown consequences. These can be issues such as delayed

[848] OPERATIONAL GUIDANCE FOR K-12 SCHOOLS AND EARLY CARE AND EDUCATION PROGRAMS TO SUPPORT SAFE IN-PERSON LEARNING, CTRS. FOR DISEASE CONTROL AND PREVENTION (last updated Oct. 4, 2023).
[849] *Coronavirus disease (COVID-19): Children and masks,* WORLD HEALTH ORG. (Mar. 7, 2022).
[850] *Id.*
[851] *Id.*

speech and language disorders in young children. Many children that wore masks were more hesitant to talk with a mask on, further substantiating insecurities in communication.[852]

COVID-19 did not affect children at the same rate as adults. A May 2020 *Journal of the American Medical Association* [hereinafter "JAMA"] review of North American pediatric hospitals article published, "[o]ur data indicates that children are at far greater risk of critical illness from influenza than from COVID-19."[853] COVID-19 was far less serious for children than it was for adults.

Yet even with the early knowledge children were not as suspectable to the virus, many students were subjected to wearing masks for much longer than necessary. Further, in 2022, the CDC did not list speech or language impairments as an adequate reason for a mask exemption for schools.[854] The consequences of this are already being felt. The American Speech-Language-Hearing Association published a 2023 survey that concluded two-thirds of participating speech-language pathologists reported in increase in client referrals since 2020.[855]

Ignoring the science and facts of COVID-19 and the harms of masking young children was profoundly immoral on behalf of the leadership of the country's public health officials. The future consequences of these types of draconian policies are not yet known, but public health leaders in the future should remember that all policy must be decided in a balanced manner.

[852] Stephanie H. Murray, *Speech Therapy Shows the Difficult Trade-Offs of Wearing Masks,* THE ATLANTIC (Mar. 2, 2022).
[853] Lara S. Shekerdemian, *et al., Characteristics and Outcomes of Children With Coronavirus Disease 2019 (COVID-19) Infection Admitted to US and Canadian Pediatric Intensive Care Units*, JAMA (May 2020).
[854] Stephanie H. Murray, *Speech Therapy Shows the Difficult Trade-Offs of Wearing Masks*, THE ATLANTIC (Mar. 2, 2022).
[855] Liza Stahnke, *Elusive Words: Confronting the Post-Pandemic Skills Gap*, ASHAWIRE (May 17, 2024).

VI. Unscientific COVID-19 Lockdowns Caused More Harm Than Good

The COVID-19 pandemic proved to be one of the most consequential events in modern American history. Yet, the virus itself may not have the same lasting effects to health, culture, and the economy as the government's policy response. From the local to the federal level, policies aimed at fighting COVID-19 had tremendous unintended consequences and side-effects that we will likely be dealing with for generations to come. One of the most controversial and consequential of these pandemic-era policies were the stay-at-home orders and other social distancing policies generally referred to as "lockdowns." Later in the pandemic a new de facto lockdown emerged for unvaccinated Americans in many parts of the country with mandatory vaccination policies often referred to as "vaccine passports." Most federal lockdown policies were nonbinding guidelines for states to use to inform their own policy, though they directly led to stringent lockdowns which were executed with the force of law in many states.

On March 16, 2020, the Trump Administration announced "15 days to slow the spread" guidelines. Subsequent to these guidelines, states and localities took it a step further and began to issue strict lockdown orders.[856] At this point, there appeared to be general agreement that potentially unnecessary activities should be put on hold temporarily to "flatten the curve" and mitigate the risk of the healthcare system being overwhelmed by serious cases of COVID-19. Yet, behind the scenes public health officials were quietly preparing for a much longer period of disruption. Dr. Birx later wrote in her book "Silent Invasion" that 15 days was simply a starting point and that she had already planned for a longer lockdown when pitching the plan.

> No sooner had we convinced the Trump administration to implement our version of a two-week shutdown than I was trying to figure out how to extend it. Fifteen Days to Slow the Spread was a start, but I knew it would be just that. I didn't have the numbers in front of me yet to make the case for extending it longer, but I had two weeks to get them.[857]

Ultimately, the promised 15 days evolved into years, which caused incredibly damaging consequences for the American people. Rather than prioritizing the protection of the most vulnerable, federal and state government policies encouraged or forced millions of Americans to forego critical elements of a healthy, happy, productive, and fulfilling life. This appears to be a fundamental problem with the public health approach favored by American institutions during the pandemic. In an apparent *mea culpa* from Dr. Collins on a panel for Braver Angels, he admitted that the approach inherently disregarded possible collateral damage and blindly sought to fight COVID itself.

> You attach infinite value to stopping the disease and saving a life. You attach zero value to whether this actually totally disrupts people's lives, ruins the

[856] Press Release, White House, 15 Days to Slow the Spread (Mar. 16, 2020).
[857] David R. Henderson, *Book Review: Silent Invasion*, CATO INSTITUTE (Spring 2023).

> economy, and has many kids kept out of school in a way that they never quite recovered.[858]

As more data comes out about the elements to which the public health establishment attached "zero value," it appears the American people could have been better served by policies which focused on protecting the most vulnerable while prioritizing productivity and normalcy for the less vulnerable.

FINDING: Enduring COVID-19 Lockdowns Unnecessarily Harmed the U.S. Economy.

Potentially the most severe consequence of COVID-19 lockdowns was the damage they caused to the economy. In the wake of COVID-19 lockdowns, businesses closed, workers were laid off, and inflation soared. The lockdowns also disproportionately disrupted service industry jobs, thereby doubly punishing lower wage earners across the country while professional and business sectors shifted to remote work. Meanwhile, shifting consumer habits and disrupted supply chains helped to pump up the stock market and drive-up profits for large corporations and wealthy individuals. As a result of lockdowns, millions of Americans experienced new and painful economic hardship. This Report contains more more detail about the economic destruction during the pandemic.

FINDING: Enduring COVID-19 Lockdowns Unnecessarily Damaged American's Mental Health.

Enduring COVID-19 lockdowns had drastic consequences on the mental health of many Americans, including elevated substance abuse, overdoses, and suicide. The full picture of these consequences is not yet knowable as it will take years to collect and analyze the data, however currently available data already indicates incredibly troubling trends. For example, a March 2024 *Nature* study found a 22 percent increase in mental health disorders between 2019 and 2020.[859] The study also found a causal relationship between lockdowns and mental health disorders.

> Results show that lockdown has significantly and causally increased the usage of mental health facilities in regions with lockdowns in comparison to regions without such lockdowns. Particularly, resource usage increased by 18% in regions with a lockdown compared to 1% decline in regions without a lockdown.[860]

[858] Braver Angels, A Deplorable and an Elitist Walk into a Bar: Francis Collins and Wilk Wilkinson (July 10, 2023); *See also*, Scott Atlas, Steve Hanke, Philip Kerpen, & Casey Mulligan, *COVID Lessons Learned: A Retrospective After Four Years*, COMM. TO UNLEASH PROSPERITY (Mar. 2024).
[859] Ibtihal Ferwana & Lav. R Varshney*, The impact of COVID-19 lockdowns on mental health patient populations in the United States,* NATURE (Mar. 7, 2024).
[860] *Id.*

Data showing this troubling trend was available early in the pandemic. An August 2020 CDC study on mental health during the pandemic found that 40 percent of U.S. adults reported struggling with mental health or substance use.[861]

Other forms of addiction also rose dramatically during the era of lockdowns. A chapter in the textbook "Behavioral Addiction: A Comprehensive Perspective" highlighted data illustrating a troubling rise in gambling, internet gaming, pornography, social media, online dating, shopping, and food addictions.[862]

> The COVID-19 pandemic has cast a spotlight on the intricate relationship between public health crises and behavior addiction. It has underscored the need for a nuanced understanding of how stressors, isolation, and the digital age intersect to foster addiction in various forms, from smartphone and social media addiction to pornography and food addiction.[863]

Unfortunately, it also appears that many of the individuals who were the least at risk of serious illness or death from COVID-19 were at disproportionately higher risk of suffering serious mental distress as a result of lockdowns. For example, a February 2023 study, published by the *American Academy of Pediatrics*, found that suicide deaths among U.S. youth increased significantly during the pandemic, with an estimated 212 excess youth suicides occurring in 2020 alone.[864] This trend appeared even stronger with substance abuse. A December 2022 CDC study found that median monthly adolescent overdose deaths increased 109% between July-December 2019 to July-December 2021.[865]

FINDING: Enduring COVID-19 Lockdowns Disrupted the Development of American Children and Young Adults.

Reports indicate that speech delays in children are more common in the wake of the pandemic. In 2023, the American Speech and Hearing Association conducted a national poll of audiologists and speech-language pathologists who work with children under the age of five, the majority of whom reported an increase in referrals for concerns about hearing, speech, and language delays or disorders since the pandemic began.[866] Of the polled speech-language pathologists, 84 percent reported seeing more children with emotional or behavioral difficulties, 79 percent reported seeing more children with delayed language or diagnosed language

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[861] Mark É. Czeisler*, et al., Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020*, MMWR (Aug. 14, 2020).
[862] Kevin Gallagher, *Pandemic Lockdowns Led to Spike in Behavioral* Addictions, MAD IN AMERICA (Nov. 22, 2023).
[863] *Id.*
[864] Jeffrey A. Bridge, *et al., Youth Suicide During the First Year of the COVID-19 Pandemic,* PEDIATRICS (Feb. 15, 2023).
[865] Lauren J. Tanz, *et al., Drug Overdose Deaths Among Persons Aged 10–19 Years — United States, July 2019–December 2021*, MMWR (Dec. 16, 2022).
[866] *Poll Shows Increase in Hearing, Speech, and Language Referrals, More Communication Challenges in Young Children*, ASHA (Apr. 30, 2023).

disorders, and 78 percent reported seeing more children with social communication difficulties.[867]

This increase in speech and language disorders is also supported by studies conducted in the U.S. and abroad in the wake of the pandemic. Research done by Rhode Island Hospital's Advanced Baby Imaging Lab and the nonprofit LENA Foundation indicates that children under 16 months old showed a significant reduction in verbal skills between 2020 and 2021, and neuroimaging data showed that babies born during the pandemic had slower growth in the communications channels of the brain.[868] A related preprint study co-authored by the Advanced Baby Imaging Lab's Principal Director, Dr. Sean Deoni, found that children born during the pandemic had average cognitive scores of 78, down from 100 in children born before the pandemic.[869] Analysis by LENA used devices worn by children to measure the number of words spoken near the child and the child's own vocalizations in order to count child-adult interactions—a critical component of language acquisition according to researchers.[870] LENA researchers found that "children born nine months into the COVID-19 pandemic produced significantly fewer vocalizations and experienced fewer serve-and-return interactions in the first months of life than those born before the pandemic."[871]

Harmful developmental delays were not limited just to infants born during the pandemic. Due to lockdowns as well as financial hardship, more young adults became dependent on their parents during the pandemic. According to Pew Research, the share of 18–29-year-olds living at home with their parents reached 52 percent during the first year of the pandemic—surpassing the previous peak during the Great Depression.[872] Scientific studies on teenagers and young adults have also found other troubling trends associated with lockdowns. For example, a September 2024 study from the University of Washington found that COVID-19 lockdowns prematurely aged the brains of teenagers, with the trend appearing stronger in females than males.[873] The researchers said of their findings "our research introduces a new set of questions about what it means to speed up the aging process in the brain. All the best research raises profound new questions, and I think that's what we've done here."[874]

These harmful effects associated with COVID-19 lockdowns in American youth are also inexorably linked to extended school closures. This Report contains more details on the impacts of school closures.

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[867] *Id.*
[868] Sarah D. Sparks, *Babies Are Saying Less Since the Pandemic: Why That's Concerning*, EDUCATION WEEK (Apr. 7, 2022).
[869] CrisAnna Mink, Is *COVID causing developmental delays in kids?,* USC CENTER FOR HEALTH JOURNALISM (Dec. 21, 2021).
[870] Jo Napolitano, *New Research: Babies Born During COVID Talk Less with Caregivers, Slower to Develop Critical Language Skills*, THE 74 (Apr. 18, 2022).
[871] LENA Team, *COVID-era infants vocalize less and experience fewer conversational turns, says LENA research team,* LENA (Mar. 7, 2022).
[872] Richard Fry, *et al., A majority of young adults in the U.S. live with their parents for the first time since the Great Depression,* PEW RESEARCH CENTER (Sept. 4, 2020).
[873] Lauren Kirschman, *COVID-19 lockdowns prematurely aged teenage brains, UW study shows,* UW NEWS (Sept. 9, 2024).
[874] *Id.*

FINDING: Enduring COVID-19 Lockdowns Unnecessarily had Severe Consequences for Americans' Physical Health.

While COVID-19 itself was clearly a massive threat to American's health, so too were the lockdowns. One analysis done using CDC data found that non-COVID-19 excess deaths totaled nearly 100,000 per year in 2020 and 2021.[875] The findings indicate that hypertension, heart disease, and diabetes dominated the excess deaths for senior citizens, while accidents, overdoses, alcoholism, and homicide skewed younger.[876] Because of this, Americans under the age of 45 had more excess deaths without the virus in 2020 and 2021 than they had from it.

> If the pandemic response had to involve wholesale disruption of ordinary life, the public-health community should have been actively monitoring its effects on the millions of Americans we knew suffered from drug addiction, diabetes and many other potentially lethal health conditions. No time is too soon to acknowledge and begin to alleviate the collateral damage from Covid policies.[877]

Relatedly, COVID-19 lockdowns led to many procedures and doctor visits being delayed for millions of Americans. One study published in JAMA found that 41 percent of Americans had forgone medical care during the early months of the pandemic, from March to July 2020.[878] Some studies have even found that early detection of diseases such as cancer was hindered. For instance, a report published in JAMA Oncology in January 2021 found a "significant decrease in the number of patients undergoing screening tests for cancer and in the number of ensuing diagnoses of cancerous and precancerous lesions during the COVID-19 pandemic…"[879]

Disease prevention was also hindered significantly by our COVID response. Looking at cardiovascular health trends alone, it is clear how significant the damage is. One survey found that 42 percent of Americans gained more weight than they intended, with an average weight gain of 29 pounds.[880] The millions of missed appointments not only have serious implications for disease prevention and detection, but they also led to increased wait times,[881] shortened appointments, and patient burnout once things returned to normal.[882]

FINDING: Despite Lacking Scientific Basis, Vaccine Passports Became a De Facto Lockdown for Unvaccinated Americans.

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[875] Casey B. Mulligan & Robert D. Arnott, *The Young were not Spared: What Death Certificates Reveal about Non-Covid Excess Deaths,* SAGE JOURNALS (Dec. 15, 2022).
[876] *Id.*
[877] *Id.*
[878] 15 Days to Slow the Spread, *supra* note 856.
[879] David R. Henderson, *Book Review: Silent Invasion*, CATO INSTITUTE (Spring 2023).
[880] Sophie Bethune, *One year on: Unhealth weight gains, increased drinking reported by Americans coping with pandemic stress*, AMERICAN PSYCHOLOGICAL ASSOCIATION (Mar. 11, 2021).
[881] Oliver Kharraz, *Long waits to see a doctor are a public health crisis*, STAT (May 2, 2023).
[882] Jamie Ducharme, *Long Waits, Short Appointments, Huge Bills: U.S. Health Care is Causing Patient Burnout*, TIME (Feb. 27, 2023).

In 2021 and 2022, with the rollout of COVID-19 vaccines, some policies were eased, and normalcy began slowly returning in many areas of American life. However, a new de facto lockdown began to emerge across many jurisdictions for anyone who elected not to receive a COVID-19 vaccine. The Report addresses broader issue of COVID-19 vaccine mandates, but so-called "vaccine passport" policies were in some ways their own distinct policy. "Vaccine passports" refer to policies put in place which required vaccination to attend social functions—like sporting events and concerts, travel, patronize restaurants and bars, or other activities.[883] While there were a variety of methods used to verify vaccination status, among the most common was to require individuals to present their CDC issued COVID-19 vaccine cards. According to reports, the CDC issued nearly 1 billion of these cards between 2020 and May of 2023.[884]

In August 2021, New York City became the first major city to impose a vaccine passport requirement when Mayor Bill de Blasio announced that the city would require proof of vaccination for customers and employees of gyms, movie theaters, and indoor dining establishments.[885] During Mayor de Blasio's briefing announcing the policy, New York State Senator James Sanders Jr. spoke in support of the effort, saying, "you have the right to your body, of course, but you do not have the right to kill other people" and that "a strong stance needs to be taken."[886] This type of divisive rhetoric became a hallmark of the era of vaccine passport policies. Many leaders and politicians sought to characterize unvaccinated individuals as being the source of the continued pain and suffering that COVID-19 was imparting, and vaccine passports were presented as a solution. On July 16, 2021, just a month before the New York City vaccine passport policy, Dr. Walensky notoriously warned that "this is becoming a pandemic of the unvaccinated."[887]

However, COVID-19 vaccines were never intended to stop the spread of the virus, and any marginal benefit they provided in this particular realm had essentially disappeared with the outbreak of the Delta variant—which was already widely spreading among vaccinated individuals in August 2021.[888] Dr. Walensky herself acknowledged on August 5, 2021, that COVID-19 vaccines "continue to work well for Delta, with regard to severe illness and death – they prevent it. But what they can't do anymore is prevent transmission."[889] Unfortunately, even with this knowledge that the vaccines did little to prevent the spread of the disease, numerous other jurisdictions followed New York City's lead and imposed similar requirements for vaccine passports, including New Orleans, San Francisco, Philadelphia, Boston, Chicago, Washington D.C., and others.[890]

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[883] Anna Rouw, *et al., Key Questions about COVID-19 Vaccine Passports and the U*.S., KFF (Apr. 15, 2021).
[884] Ayana Archie, *The CDC will no longer issue COVID-19 vaccination cards*, NPR (Oct. 5, 2023
[885] Emma G. Fitzsimmons, *New York City to Require Proof of Vaccination for Indoor Dining and Gyms*, THE N.Y. TIMES (Aug. 3, 2021).
[886] *Id.*
[887] Emily Anthes & Alexander E. Petri, *C.D.C. Director Warns of a 'Pandemic of the Unvaccinated'*, THE N.Y. TIMES (July 16, 2021, updated July 22, 2021).
[888] Reuters Fact Check, *Fact Check: Preventing transmission never required for COVID vaccines' initial approval; Pfizer vax did reduce transmission of early variants*, REUTERS (Feb. 12, 2024).
[889] Madeline Holcombe & Christina Maxouris, *Fully vaccinated people who get a Covid-19 breakthrough infection can transmit the virus*, *CDC chief says*, CNN HEALTH (Aug. 6, 2021).
[890] Carlie Porterfield, *Here Are The U.S. Cities Where You Need A Covid Vaccine To Dine In A Restaurant*, FORBES (Dec. 22, 2021).

In the paper, "The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good," the authors argued that these sorts of "differential restrictions" were often viewed as punitive and discriminatory and had damaging effects on public trust, vaccine confidence, and political polarization.

> While vaccine mandates for other diseases exist in some settings (e.g., schools, travel (e.g., yellow fever) and, in some instances, for healthcare workers, population-wide adult mandates, passports, and segregated restrictions are unprecedented and have never before been implemented on this scale. These vaccine policies have largely been framed as offering 'benefits' (freedoms) for those with a full COVID-19 vaccination series, but a sizeable proportion of people view conditioning access to health, work, travel and social activities on COVID-19 vaccination status as inherently punitive, discriminatory and coercive.[891]

These policies which imparted "segregated restrictions" essentially created a new type of lockdown wherein unvaccinated individuals were denied the ability to return to normalcy under the incorrect assumption that they were a danger to society. This de facto lockdown also had some staying power, with some jurisdictions continuing their vaccine passport policies into 2022.[892] Even once local governments lifted the requirements, many businesses chose to continue them independently, therefore illustrating how pervasive these false assumptions about COVID-19 vaccines protective abilities had become.[893] The COVID-19 vaccines are arguably more akin to treatments than the traditional vaccines the American public is used to receiving in early childhood. The mRNA vaccines for COVID-19 did not prevent human-to-human transmission nor prevent COVID-19 infection in the way that traditional vaccines have been able to do. Not fully and honestly explaining this dynamic was a critical public health messaging failure. It is likely that COVID-19 vaccine passport policies and related divisive political rhetoric will have continued impact on Americans' perception of public health and may be a hurdle for future pandemic preparedness.

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[891] Kevin Bardosh, *et al., The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good*, BMJ GLOBAL HEALTH (May 2023) [hereinafter "Bardosh, The unintended consequences of COVID-19 vaccine policy"].
[892] New Orleans COVID Safety Plan, (last updated Apr. 19, 2022) *available at* https://www.neworleans.com/blog/post/new-orleans-covid-safety/.
[893] Kayla Benjamin, *DC's Vaccine Mandate Is Over—but Many Restaurants, Gyms, and Entertainment Venues Still Require Vax Proof*, WASHINGTONIAN (Feb. 16, 2022).

VII. Former New York Governor Andrew Cuomo's March 25 Order Was Medical Malpractice, and the New York Executive Chamber Attempted to Cover it Up

Beginning in March 2020, federal, state, and local governments rushed to respond to the COVID-19, implementing strict social distancing and stay-at-home orders aiming to limit transmission. It quickly became clear that COVID-19 was especially dangerous for elderly people and people with comorbidities. Accordingly, it was critically important that public health policy prioritize and implement targeted mitigation measures to protect high-risk populations.

Many states issued guidance intended to reduce exposure to COVID-19 for vulnerable populations in nursing homes and long-term care facilities. Namely, this included restricting individuals diagnosed with COVID-19 from accessing these facilities.

However, a handful states—including New York—failed to institute similar guidance. Instead, New York issued an order that effectively required nursing homes and long-term care facilities to admit COVID-19 positive individuals.

On March 25, 2020, the Cuomo Administration issued a directive entitled "Hospital Discharges and Admissions to Nursing Homes" [hereinafter the "March 25 Directive"].[894] The March 25 Directive ordered that "[n]o resident shall be denied re-admission or admission to the [nursing home] solely based on a confirmed or suspected diagnosis of COVID-19" and "[nursing homes] are prohibited from requiring a hospitalized resident who is determined medically stable to be tested from COVID-19 prior to admission or re-admission."[895] While other states with similar orders quickly reversed course, Mr. Cuomo failed to terminate his directive for six weeks.

As a result of the March 25 Directive, more than 9,000 COVID-19 patients were readmitted or admitted to nursing homes between March 25, 2020 and May 8, 2020.[896] This unjustifiably exposed vulnerable nursing home populations to COVID-19, causing predictable but disastrous consequences—including excess deaths.[897]

FINDING:	The Cuomo Administration's March 25 Directive Was Antithetical to Known Science.

It was well understood early in the pandemic that COVID-19 did not harm all people equally. Age and comorbidities were the most important risk factors for predicting hospitalization and death from COVID-19.

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[894] Memorandum from the N.Y. State Dep't of Health to Nursing Home Administrators, *et. al.* (Mar. 25, 2020) (on file with Select Subcomm. Staff) [hereinafter "March 25 Directive"].
[895] *Id.*
[896] Bernard Condon & Jennifer Peltz, *Over 9,000 virus patients sent into NY nursing homes*, ASSOCIATED PRESS (Feb. 11, 2021).
[897] *Id.*

The risks to elderly populations, especially those in nursing homes, were known to Mr. Cuomo.[898] Mr. Cuomo was aware of the deaths occurring in the State of Washington—the early epicenter of COVID-19—as a result of COVID-19 in nursing homes.[899] On March 10, 2020, in response to a question regarding the threat COVID-19 posed to nursing homes, he stated that coronavirus in nursing homes was a "nightmare" scenario.[900]

> [T]hat's my nightmare and that's where you're going to see the pain and the damage from this virus. Senior citizen homes, nursing homes, congregant senior facilities…[901]

Days later, Mr. Cuomo allegedly told Mr. Jared Kusher—who helped lead the early White House response to COVID-19—that "[f]or nursing homes, ***this could be like fire through dry grass***."[902]

The Cuomo Administration initially took actions to safeguard vulnerable populations, including suspending visitation to nursing homes[903] and ordering vulnerable populations to stay home while restricting visitors.[904] Nonetheless, the Cuomo Administration still issued the March 25 Directive. These other actions demonstrate that Mr. Cuomo and his Administration knew the dangers of COVID-19 to nursing homes but proceeded with the March 25 Directive regardless.

Finding:	Contrary to Denials, Mr. Andrew Cuomo and the New York Executive Chamber Were Directly Involved in the Decision that Led to the March 25 Directive.

In a transcribed interview, Dr. Zucker testified that the March 25 Directive was prompted by a phone call Mr. Cuomo received from GNYHA.

> **Dr. Howard Zucker (December 18, 2023)**
>
> Q. When you did ask questions did you ever ask what prompted the directive to be drafted?
>
> A. I know why this was drafted. I know why this was drafted.
>
> Q. Can you just briefly summarize?

[898] Marisa Kwiatkowski, *'A national disgrace': 40,600 deaths tied to US nursing homes*, USA TODAY (June 1, 2020).
[899] Andrew Cuomo, American Crisis: Leadership Lessons from the COVID-19 Pandemic (Crown Publishing Group, Oct. 13, 2020).
[900] The Lead with Jake Tapper, CNN (Mar. 10, 2020).
[901] *Id.*
[902] Steven Nelson & Bernadette Hogan, *Cuomo feared COVID 'fire' in nursing homes before notorious order: Kushner*, N.Y. POST (Aug. 2, 2022) (emphasis added).
[903] Letter from N.Y. State Dep't of Health, to Nursing Homes and Adult Care Facilities (Mar. 13, 2020).
[904] *Governor Cuomo Signs the 'New York State on PAUSE' Executive Order*, Gov. Kathy Hochul (Mar. 20, 2020).

A. Sure. Sure. So it goes to what was transpiring at the time. So we have to put this in context. And now we're in March, the middle of March, and the numbers are going up. The third week of March the cases were escalating at a rapid pace, and I would wake up in the morning with 1,000 more positive cases, and unbelievable numbers of people being admitted to the hospital. But a few days before this was drafted, or sent out I should say, the modelers came back with what is going to happen. So the governor asked for the public health expert modeling teams that were consultants to provide us with where this was going, and they predicted up to 136,000 people would be in the hospital at peak, which was X number of weeks away. I don't remember, 4, 6 weeks away from where we were at that point. And when I looked at the rate at which people were going to the hospital it made sense that we could end up there. And at that point, we also had, around this same time, a crisis at Elmhurst Hospital, where they had about 234 positive people in the hospital with COVID out of their 400-or-so beds, and 13 had died in one 24-hour period. And the hospitals were getting overwhelmed. Greater New York Hospital Association called the governor and the team – we were all there in a conversation; a lot of us were there – and said that we have individuals who are better, they have recovered, and they are just sitting in a hospital bed but they need to go "home," quote "home" for those who are in long-term care facilities or the other ones would just go home. And the long-term care facilities were not going to take them and that we needed to do something, which generated this document…[905]

Dr. Zucker testified that he was not involved with the drafting, review, or issuance of the March 25 Directive, but said that issuing an advisory, that would become the March 25 Directive, was decided following the GNYHA's phone call with Mr. Cuomo.

Dr. Howard Zucker (December 18, 2023)

Q. …When did you first see a copy [of the directive]?

A. So I actually do not remember seeing this advisory. I was there, along with others, from the Governor's Office when the decision was made to issue an advisory, and then it was put into motion…[906]

[905] Transcribed Interview of Howard Zucker, M.D., Former Commissioner, N.Y. State Dep't of Health, at 88-89 (Dec. 18, 2023) [hereinafter "Zucker TI"]; *See also,* Jimmy Vielkind, *et. al.*, *In Worst-Hit COVID State, New York's Cuomo Called All the Shots*, WALL STREET JOURNAL (Sept. 11, 2020) (Reported that "Mr. Raske, president of the Greater New York Hospital Association, said he contacted Mr. Cuomo's team for help with nursing homes. Hospitals couldn't afford to house recovered nursing-home residents long-term, with models showing they soon could be swamped.").

[906] Zucker TI, *supra* note 905, at 93.

In a transcribed interview, Mr. Cuomo testified that he played no role in the issuance of the March 25 Directive and was not aware of it until he was asked about it at a press conference on April 20, 2020.[907] Mr. Cuomo testified that he did not recall receiving a phone call from the GNYHA related to discharging hospitalized individuals to nursing homes.[908] However, Mr. Cuomo testified that his discussions with GNYHA were "always" related to hospital capacity—the issue the March 25 Directive was purportedly drafted to correct.

Mr. Andrew Cuomo (June 11, 2024)

Q. Do you recall such a phone call taking place?

A. No.

Q. Regardless of the phone call, do you recall the Greater New York Hospital Association asking you to do something related to that issue?

A. No. The discussion with the Greater New York Hospital Association was always about the hospital capacity and they were tracking the capacity, which never actually happened.

Q. As far as hospital capacity is concerned, would it be possible that they would have proposed something similar to the March 25 order in order to increase hospital capacity?

A. No. I'll use the analogy I used before. Fire capacity is 41 in this room. It's not a problem until the 42nd person shows up. Then it will be a discussion, but we never – that never happened.[909]

At a transcribed interview, Ms. DeRosa testified that she played no role in the development of the March 25 Directive and only learned about it at the press conference on April 20, 2020.[910] Ms. DeRosa speculated that it was drafted by a "midlevel person" within NYSDOH.[911]

At a transcribed interview, Mr. Hutton testified that the March 25 Directive was developed by NYSDOH staff.[912] Similar to Dr. Zucker, Mr. Hutton testified that the March 25

[907] Transcribed Interview of Andrew Cuomo, Former Governor, State of N.Y., at 38-41 (June 11, 2024) [hereinafter "Cuomo TI"].
[908] Cuomo TI, *supra* note 907, at 202-203.
[909] *Id*.
[910] Transcribed Interview of Melissa DeRosa, Former Sec'y to the Governor, State of N.Y., at 20 (June 21, 2024) [hereinafter "DeRosa TI"].
[911] *Id.* at 114-115.
[912] Transcribed Interview of Bradley Hutton, Former Deputy Commissioner, N.Y. State Dep't of Health, at 26-28 (Aug. 27, 2024) [hereinafter "Hutton TI"].

Directive was prompted by "an urgent phone call from the [Chief Executive Officer] of a hospital in the Hudson Valley" that was concerned about hospital capacity.[913]

FINDING:	The New York Executive Chamber Reviewed and Approved the March 25 Directive.

Mr. Hutton testified that the March 25 Directive "absolutely" received approval from the Executive Chamber prior to issuance.

Mr. Brad Hutton (August 27, 2024)

Q. … [T]he Executive Chamber signs off on all Health Department guidance that was issued. Is that right?

A. In the pandemic, yes.

Q. So, for the record, the March 25th order did receive sign-off from the Executive Chamber?

A. Yes, absolutely. [914]

Similarly, Dr. Zucker testified all NYSDOH guidance needed to be approved by the Executive Chamber.

Dr. Howard Zucker (December 18, 2023)

Q. …[D]o you agree with Ms. DeRosa's characterization of the Department's practices in issuing guidance?

A. I would say that during this pandemic everything ended up on the second floor.

Q. Can you elaborate on that?

A. Yeah, well, the second floor being the Executive Chamber, the governor's floor.

Q. So it's –

A. And there were times when we, the Department of Health, would say, "Where is that guidance?" and it still hasn't been cleared from over on the second floor.

[913] *Id*.
[914] Hutton TI, *supra* note 912, at 51.

Q. And when you say "second floor" –

A. That is the Governor's Office. Sorry.

Q. Okay. Would you presume that would include the governor himself being privy to—

A. I can't answer how that process went. We knew that things needed to be cleared, and sometimes they were legal issues, which Beth Garvey was involved, and other issues, obviously, the secretary to the Governor, Melissa DeRosa, was the one who signed off on it.[915]

Furthermore, according to Dr. Zucker, "most things" had to be approved by Ms. DeRosa, herself. However, Dr. Zucker did not testify that Ms. DeRosa approved the March 25 Directive.

Dr. Howard Zucker (December 18, 2023)

Q. During the pandemic did anyone in the Governor's Chamber, Ms. DeRosa included, act as a clearinghouse of information?

A. Well, everything ended up having to go through the Governor's Office. And when I use the phrase "governor's office" I refer to the entire, you know, the executive team, the second floor, however one wants to refer to it. But that's what I mean when I say "governor's office."

Q. What did that look like? Did you like a stamp of approval? Who gave the final stamp of approval on issuing something?

A. Well, most things went through the secretary to the governor, Melissa DeRosa. That was, I guess, in a lot of ways, the voice of what the governor wants, right? And we moved forward on addressing whatever the challenges were.[916]

According to documents, Ms. DeRosa did serve as "final sign off" on at least one guidance relating to nursing homes and visitation.[917]

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[915] Zucker TI, *supra* note 905, at 43-44.
[916] *Id*. at 22-23.
[917] E-Mail from Executive Chamber Staff to Executive Chamber Staff (July 7, 2020, 3:01 PM).

From: [redacted]
Sent: Tuesday, July 07, 2020 3:01 PM
To: [redacted]
Cc: [redacted]
Subject: MDR for final sign off

Nursing Homes

- Criteria to allow visitation:
  - Nursing Home must be in phase 3 region.
  - No COVID cases among residents or staff for 28 days (currently 146 nursing homes would qualify*)
  - The nursing home must be in full compliance with all state and federal requirements, have access to adequate testing, have agreements with laboratories to process tests, and have no staffing shortages.
  - A formal copy of visitation plan must be posted to website and broadcast to visitors
- Visitation is limited to outdoor areas, except under certain circumstances where visitation may be inside in a well-ventilated space with no more than 10 individuals
- The number of visitors must not exceed ten percent (10%) of the resident census at any time and only one visitor will be allowed per resident at any one time.
- Visitors must wear proper PPE and must be screened for signs and symptoms of COVID-19 prior to visitation
- The Department can halt visitation at the nursing home at any time due to community or facility spread of infection or when the Department identifies that the NH has failed to comply with visitation requirements.

Pediatric Nursing Homes

- Same criteria as for allowing visitation as Nursing Homes except, pediatric nursing homes in all regions of the state are eligible, regardless of phase
- Same procedures for visitation as nursing homes plus:
  - Visitation is limited to parents or legal guardians of the resident and immediate family ages 18 and older.
  - Two visitors per resident are permitted at one time (compared to one for nursing homes)

Adult Care Facilities

- Visitation criteria is the same as for nursing homes plus ACF must have undergone an infection control survey since May 1, 2020 and must have been found to be in substantial compliance
  - Currently 328 ACFs would qualify*
- When those criteria are met, ACFs may have the same visitation as nursing homes plus:
  - resume congregate activities that do not include eating and drinking
  - allow salon services that abide by NY Forward guidance specific to salons and barbershops

*Number of facilities could change as pending staff and resident test results come back

At a transcribed interview, Ms. Garvey testified that she had a role in the approval of the March 25 Directive.

Ms. Beth Garvey (May 30, 2024)

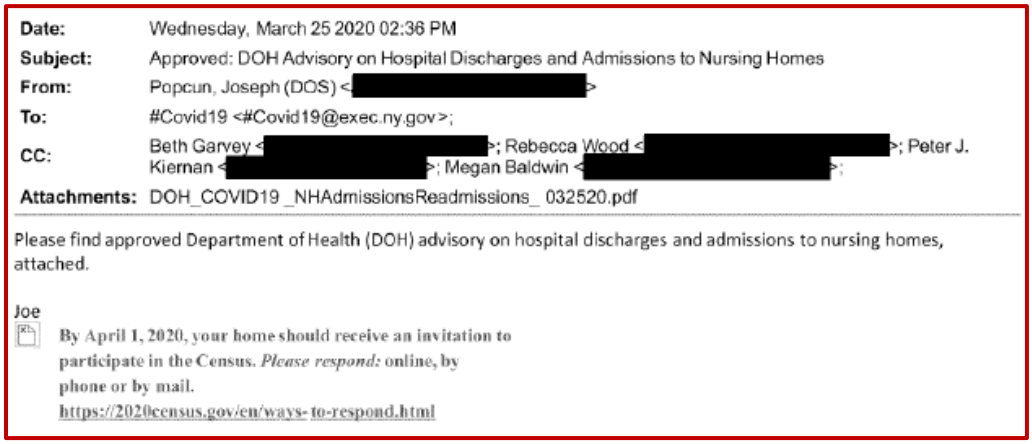
Q. Did you play any role in the development of this guidance?

A. Yes.

Q. Can you explain your role?

A. Um, so I have no specific memory of this, but as I stated earlier, guidance was coming to the Executive Chamber and it was being reviewed by a number of different staff people and ultimately coming to me for approval to go out. It did typically run through Joe Popcun, who sent this e-mail. He was deployed, you know, from Department of State to help our office. And so I would have looked at this guidance to make sure that it was consistent with executive orders, policies, every, you know, communication that the Governor was making and then approved it for distribution by whatever department had asked for the guidance.[918]

Indeed, the approved March 25 Directive was attached in an email from Mr. Joseph Popcun to several Executive Chamber officials, including Ms. Garvey, Ms. Rebecca Wood, Mr. Peter Kiernan, and Ms. Megan Baldwin.[919]



Date: Wednesday, March 25 2020 02:36 PM
Subject: Approved: DOH Advisory on Hospital Discharges and Admissions to Nursing Homes
From: Popcun, Joseph (DOS) <[redacted]>
To: #Covid19 <#Covid19@exec.ny.gov>;
CC: Beth Garvey <[redacted]>; Rebecca Wood <[redacted]>; Peter J. Kiernan <[redacted]>; Megan Baldwin <[redacted]>;
Attachments: DOH_COVID19 _NHAdmissionsReadmissions_ 032520.pdf

Please find approved Department of Health (DOH) advisory on hospital discharges and admissions to nursing homes, attached.

Joe

By April 1, 2020, your home should receive an invitation to participate in the Census. *Please respond:* online, by phone or by mail.
https://2020census.gov/en/ways- to-respond.html

At a transcribed interview, Ms. Lacewell testified that Mr. Cuomo and Ms. DeRosa were "surprised" by the March 25 Directive and cited the March 25 Directive as a rare example of an

[918] Transcribed Interview of Beth Garvey, Former Special Counsel to the Governor, State of N.Y., at 81-82 (May 30, 2024) [hereinafter "Garvey TI"].
[919] E-Mail from Joseph Popcun, N.Y. Dep't of State, to Beth Garvey, Special Counsel to the Governor, *et. al.* (Mar. 25, 2020).

instance when something was issued without sign-off from Ms. DeRosa.[920] Ms. Lacewell testified that this was not "supposed to happen."

Ms. Linda Lacewell (May 31, 2024)

Q. Do you think it would be fair to say nothing got approved without Ms. DeRosa's approval?

A. Well, actually things did get approved without Melissa DeRosa, but that wasn't supposed to happen.

Q. Do you have an example of that?

A. I do.

Q. Can you share?

A. I can.

Q. Please go ahead.

A. Um, the March guidance. The governor and Ms. DeRosa were not – let me rephrase that. They were surprised by the guidance. So to the best of my understanding, they were not consulted, and she was not consulted more specifically beforehand because she was surprised. And from time to time, that did happen.[921]

For her part, Ms. Lacewell testified that she had a "privileged" discussion regarding the March 25 Directive prior to its issuance with Mr. Schwartz, who formerly served as the Secretary to the Governor and volunteered to assist with the Cuomo Administration's response to the pandemic.

Ms. Linda Lacewell (May 31, 2024)

Q. What were the nature of the conversations of COVID-19 and the nursing homes with Mr. Schwartz?

A. Well, he was part of the group assembled in the Executive Chamber to manage COVID. So we regularly had conversations with each other in the day-to-day management of the pandemic during that period of time.

Q. Anything specific to the directive or nursing homes?

[920] Transcribed Interview of Linda Lacewell, Former Superintendent, N.Y. State Dep't of Health, at 42-43 (May. 31, 2024) [hereinafter "Lacewell TI"].
[921] *Id*.

…

A. Other than privileged conversations, I don't have anything for you.

Q. What was the topic of the privileged conversations?

…

A. Nursing homes.

Q. I think we can get a little bit more specific with that without touching a privileged conversation right now. So—

A. I had privileged conversation [sic] with Mr. Schwartz about the subject matter of the March directive before it was issued.[922]

In a transcribed interview, Mr. Schwartz testified that he did not recall having any conversations, privileged or otherwise, with Ms. Lacewell related to the March 25 Directive.[923] He also testified that he did not know the origins of the March 25 Directive.[924]

FINDING: The March 25 Directive Was Inconsistent with Applicable Federal Guidance Regarding Hospital to Nursing Home Transfers and COVID-19 Related Infection Control.

Mr. Cuomo and the Executive Chamber repeatedly argued that the March 25 Directive followed federal guidance, from both CMS and CDC, regarding protecting residents in nursing homes and other long-term care facilities.[925] Mr. Cuomo argued that it was "written from CMS and CDC." This testimony is contradicted by federal health officials—including and Dr. Birx.

Mr. Andrew Cuomo (June 11, 2024)

Q. I'm talking about this directive right now and the wording of the directive.

…

A. It was written from CMS and CDC. And it refers to – it is referring to the guidance they received two days before, which says, "When should a nursing home accept a resident who is diagnosed with COVID-19 from a hospital? A nursing home can accept a resident

[922] *Id*. at 20-21.
[923] Transcribed Interview of Larry Schwartz, Former Senior Advisor to the Governor, State of N.Y., at 12-13 (June 24, 2020) [hereinafter "Schwartz TI"].
[924] *Id*. at 13.
[925] *See generally* Cuomo TI, *supra* note 907.

diagnosed with COVID-19 and still under transmission-based protocol." So still infections, as long as the facility can follow CDC guidance for transmission-based precautions. If they can't, they can't take the person.[926]

Similarly, Dr. Zucker testified that the March 25 Directive was consistent with CMS and CDC guidance.

Dr. Howard Zucker (December 18, 2023)

A. …But the fact is we followed the CDC guidance that was out at the time, and CMS guidance, and the guidance, the CDC guidance about transmissible disease at that point, said that those individuals were not infectious, based on the criteria…[927]

None of the witnesses interviewed by the Select Subcommittee consulted—nor knew of anyone within the Cuomo Administration that consulted—CMS or CDC prior to the issuance of the March 25 Directive.

In response to the Cuomo Administration's insistence that the March 25 Directive followed federal guidance, Administrator Verma disagreed, saying, "[u]nder no circumstances should a hospital discharge a patient to a nursing home that is not prepared to take care of those patient's needs."[928]

Indeed, CMS guidance entitled, "For Infection Control and Prevention of Coronavirus Disease 20219 (COVID-19) in Nursing Homes" [hereinafter "CMS Guidance"] did not mandate COVID-19 positive patients back to nursing homes but, instead, stated that a COVID-19 case at a hospital does not preclude the nursing home from accepting a COVID-19 negative patient.[929] This is contrary to the March 25 Directive—which states that nursing homes shall not deny COVID-positive patients because of their COVID-19 diagnosis.[930]

In a transcribed interview, Dr. Birx, when asked about the March 25 Directive, testified that it "violated" CMS guidance.

Dr. Deborah Birx (October 13, 2021)

Q. On the bottom of page 4 of this CMS guidance it gives guidance on how to return a resident diagnosed with COVID-19 back to their nursing home; and it says it should be done if a facility can follow

[926] *Id.* at 129.
[927] Zucker TI, *supra* note 905, at 90-91.
[928] Charles Creitz, *Medicare chief Verma blasts Cuomo for trying to deflect blame onto White House for NY nursing home deaths*, FOX NEWS (May 28, 2020).
[929] Memorandum from David R. Wright, Dir., Quality, Safety & Oversight Group, U.S. Centers for Medicare & Medicaid Services, to State Survey Agency Directors (Mar. 13, 2020) (on file with Comm. Staff).
[930] March 25 Directive, *supra* note 894.

CDC guidance for transmission-based precautions. First, what would those transmission-based precautions have been?

A. So that would require isolation and gowning, masking, and ensuring no contact with any other residents.

Q. [CMS] Administrator [Seema] Verma said about this guidance, 'under no circumstances should a hospital discharge a patient to a nursing home that is not prepared to take care of those patient's needs.'

A. Correct.

Q. If we turn now to the New York Guidance…Does that have the same qualifier of able to take CDC precautions as the CMS guidance required?

A. No.

Q. So, would [the March 25 Directive] have violated CMS guidance?

A. Yes.[931]

Dr. Birx further testified to the negative effects of readmitting potentially positive COVID-19 nursing home residents.

Dr. Deborah Birx (October 13, 2021)

Q. Do you think admitting potentially positive COVID-19 nursing home residents back into the nursing home without the ability to quarantine or isolate them is dangerous and could lead to unnecessary deaths?

A. Yeah, I think that's why the CDC guidance was very clear about precautions needed to protect them. And I think that's why [CMS Administrator] Seema [Verma] was proactively working on this infection control guidance.[932]

CMS Guidance was understood as non-binding and used non-prescriptive language such as "can" and "should."[933]

[931] Transcribed Interview of Deborah Birx, M.D., COVID-19 Response Coordinator at 119-121 (Oct. 13, 2021).
[932] *Id.* at 123.
[933] Zucker TI, *supra* note 905, at 90-91.

When should a nursing home accept a resident who was diagnosed with COVID-19 from a hospital?
A nursing home can accept a resident diagnosed with COVID-19 and still under Transmission-Based Precautions for COVID-19 as long as the facility can follow CDC guidance for Transmission-Based Precautions. If a nursing home cannot, it must wait until these precautions are discontinued. CDC has released Interim Guidance for Discontinuing Transmission-Based Precautions or In-Home Isolation for Persons with Laboratory-confirmed COVID-19.

Note: Nursing homes should admit any individuals that they would normally admit to their facility, including individuals from hospitals where a case of COVID-19 was/is present. Also, if possible, dedicate a unit/wing exclusively for any residents coming or returning from the hospital. This can serve as a step-down unit where they remain for 14 days with no symptoms (instead of integrating as usual on short-term rehab floor, or returning to long-stay original room).

Conversely, the March 25 Directive referred to itself as a "directive" and used prescriptive language such as "must," "shall," and "prohibit."[934] In fact, it underlined the operative language.[935]

No resident shall be denied re-admission or admission to the NH solely based on a confirmed or suspected diagnosis of COVID-19. NHs are prohibited from requiring a hospitalized resident who is determined medically stable to be tested for COVID-19 prior to admission or readmission.

Mr. Hutton testified that it was an established "norm" to include prescriptive language, as the Executive Chamber did not like to be "perceived as being too soft or suggestive as opposed to directive."

Mr. Brad Hutton (August 27, 2024)

Q. …When you look at the last two paragraphs that we reviewed that uses permissive language such as "should" or "can," whereas the March 25th Order uses restrictive language such as "shall" or "must," is that – was the language that was used in the March 25th order ever discussed during your review?

A. I don't recall.

Q. Did you have any concerns with the language that was used in the order?

A. I didn't, but I guess I would qualify it by saying that it had been established as the norm, that this Executive Chamber preferred the orders be much more directive in their language and that we would

[934] March 25 Directive, *supra* note 894; *See also,* 'Like Fire Through Dry Grass: Nursing Home Mortality and COVID-19 Policies,': Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 1 (May 17, 2023) (Written Testimony of Bill Hammond, Senior Fellow for Health Policy, Empire Center for Public Policy) [hereinafter "Like Fire Through Dry Grass"].
[935] *Id.*

commonly receive things sent back if they were perceived as being too soft or suggestive as opposed to directive.

Q. And you said that was an executive order – or Executive Chamber suggestion?

A. I would say a norm, yeah, a norm that this Executive Chamber did not react favorably to soft or what they perceived as weak or suggestive language but instead, whether it was local health departments or nursing homes or any other entity, that we be much more directive in our language when we issue guidance.[936]

FINDING: The Cuomo Administration Terminated the March 25 Directive in Response to Public Pressure, not a Change in Applicable Science.

Despite testifying that he was not involved with the issuance, Dr. Zucker stood by the March 25 Directive.

Dr. Howard Zucker (Dec. 18, 2023)

Q. …On February 19, 2021, you defended the state's decision to issue the March 25th directive, stating, "We would make the same decision again." For the record, do you stand by that, still?

A. I do.[937]

Mr. Cuomo testified that, prior to being briefed by Dr. Zucker, he did not initially understand the March 25 Directive.

Mr. Andrew Cuomo (June 11, 2024)

Q. Going back to when you were first made aware and debriefed and Dr. Zucker you said answered questions. What questions did you ask? Did you have –

A. Well, all the questions you're asking.

Q. So you did have concerns about the directive?

A. I didn't understand it.[938]

[936] Hutton TI, *supra* note 912, at 60.
[937] Zucker TI, *supra* note 905, at 169-170.
[938] Cuomo TI, *supra* note 907, at 152.

However, Mr. Cuomo testified that he had no concerns with the March 25 Directive once Dr. Zucker explained it to him.

Mr. Andrew Cuomo (June 11, 2024)

Q. Were you concerned about the language of the [March 25] directive when it was first brought to your attention?

A. When [Dr. Zucker] explained it to me, no. Because he explained it to me in the context of the CMS/CDC…[939]

The March 25 Directive remained in effect until it was superseded by an Executive Order on May 10, 2020.[940] Ms. DeRosa testified that the Cuomo Administration did not have any discussions related to rescinding the March 25 Directive until the days leading up to the Executive Order on May 10.

Ms. Melissa DeRosa (June 21, 2024)

Q. When did you have discussion related to rescinding the order?

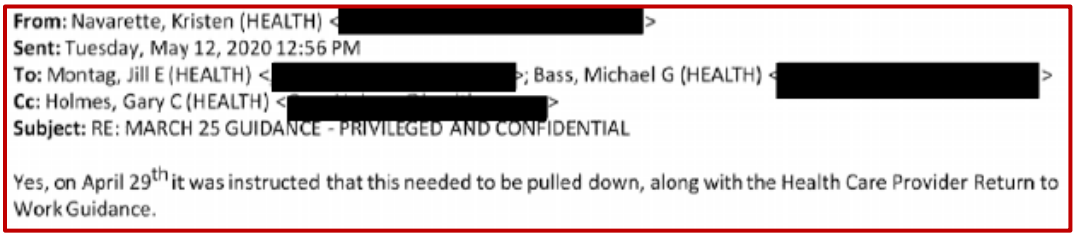
A. You're using the word rescinding. I would use the word superseding.

…

Q. When did those discussions begin?

A. I believe we did the superseding order on May 10th. So in the days leading up to May 10th.[941]

According to emails, NYSDOH was instructed to remove the March 25 Directive from its website on April 29, 2020, despite the March 25 Directive still being operable.[942]



From: Navarette, Kristen (HEALTH) <[redacted]>
Sent: Tuesday, May 12, 2020 12:56 PM
To: Montag, Jill E (HEALTH) <[redacted]>; Bass, Michael G (HEALTH) <[redacted]>
Cc: Holmes, Gary C (HEALTH) <[redacted]>
Subject: RE: MARCH 25 GUIDANCE - PRIVILEGED AND CONFIDENTIAL

Yes, on April 29th it was instructed that this needed to be pulled down, along with the Health Care Provider Return to Work Guidance.

[939] Cuomo TI, *supra* note 907, at 153.
[940] N.Y. Exec. Order No. 202.30 (May 10, 2020).
[941] DeRosa TI, *supra* note 910, at 115-116.
[942] E-Mail from Kristen Navarette, N.Y. State Dep't of Health, to Jill Montag, N.Y. State Dep't of Health, *et. al.* (May 12, 2020).

In a subsequent email, another NYSDOH official said they were instructed by the Executive Chamber to remove it because it was "inconsistent."[943]

Date: Wednesday, May 27 2020 04:32 PM
Subject: RE: KRISTEN? RE: MARCH 25 GUIDANCE - PRIVILEGED AND CONFIDENTIAL
From: Mazeau, Adrienne V (HEALTH)
To: Navarette, Kristen (HEALTH) <[redacted]>; Montag, Jill E (HEALTH) <[redacted]>;
CC: Bass, Michael G (HEALTH) <[redacted]>; Holmes, Gary C (HEALTH) <[redacted]>;

Yes because it was inconsistent and we were directed by Chamber to pull it . I can try to find emails on this.

Mr. Cuomo testified that the March 25 Directive was terminated because of "public relations."

Mr. Andrew Cuomo (June 11, 2024)

Q. But yet you rescinded the order on May 10. Talking about the decision-making process—

A. Because the public relations after April 20 had made the public so nervous and so concerned, anyone who had family in a nursing home was agitated and frightened.

Q. Did you discuss those public relations in these articles with your team?

A. I spoke to Dr. Zucker about it.

Q. Who else?

A. Basically Dr. Zucker. And I said, "Look, it may be false, but we have a lot of concerned people out there now." And it was coincident with we have ramped up our testing capacity. So we could now actually test nursing home staff, which was what he believed and I believed it was really all about.[944]

Similarly, Dr. Zucker testified that the Cuomo Administration reversed the policy in response to criticism surrounding the March 25 Directive and maintained that it was not changed because of issues with the March 25 Directive, itself.

Dr. Howard Zucker (December 18, 2023)

Q. …[I]f the March 25th guidance wasn't wrong, then why change it?

[943] E-Mail from Adrianne Mazeau, N.Y. State Dep't of Health, to Kristen Navarette, N.Y. State Dep't of Health, *et. al.* (May 27, 2020, 4:32 PM).
[944] Cuomo TI, *supra* note 907, at 158

A. It was not changed because of this guidance. It was changed more because there was such criticism about something which we felt there shouldn't be criticism on, as I was just saying. But it's not going to hurt anyone, and we're not sort of, you know, jeopardizing someone else's care by running a test on this person.[945]

FINDING: Cuomo Administration Officials Believed Mr. Cuomo Directed the Issuance of the "July 6 Report" to Combat Criticism of the March 25 Directive.

The Select Subcommittee investigated allegations that the Cuomo Administration improperly withheld and misrepresented nursing home fatality data from the public and federal government throughout the pandemic. This investigation included the drafting and publication of the NYSDOH report entitled, "Factors Associated with Nursing Home Infections and Fatalities in New York State During the COVID-19 Global Health Crisis" [hereinafter "July 6 Report"].[946]

The July 6 Report alleged that it was the nursing home staff—not the March 25 Directive—that was the source of transmission that resulted in deaths of nursing home residents.[947] However, this report was heavily edited by the Executive Chamber—including Mr. Cuomo—to show more causality and was not a scientific nor peer-reviewed publication. The Executive Chamber also made the decision to remove deaths occurring to nursing home residents out-of-facility—i.e., deaths occurring to residents that died following a transfer to the hospital—thereby releasing a report that was not fully transparent regarding deaths occurring to nursing home residents.

The origin of the July 6 Report was likely an e-mail on June 7, 2020. In that e-mail, Ms. Benton told Dr. Malatras, Mr. Rhodes, Dr. Zucker, and Ms. DeRosa that the criticism surrounding the March 25 Directive would be "the great debacle in the history books."[948] The email directed them to "[g]et a report on the facts because this legacy will overwhelm any positive accomplishment."[949]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[945] Zucker TI, *supra* note 905, at 159.
[946] *Factors Associated with Nursing Home Infections and Fatalities in New York State During the COVID-19 Global Health Crisis*, N.Y. STATE DEP'T OF HEALTH (July 6, 2020).
[947] *Id.*
[948] E-Mail from Stephanie Benton, Executive Assistant to the Governor, to Dr. Jim Malatras, Advisor to the Governor, *et. al.* (June 7, 2020).
[949] *Id*.

From: Stephanie Benton <[redacted]>
Sent: Sunday, June 07, 2020 9:51 AM
To: Jim Malatras <[redacted]>; Gareth Rhodes (dfs.ny.gov) <[redacted]>; Howard A Zucker (health.ny.gov) <[redacted]>
Cc: Melissa DeRosa <[redacted]>
Subject:

This is going to be the great debacle in the history books. The longer it lasts the harder to correct. We have a better argument than we made. Get a report on the facts because this legacy will overwhelm any positive accomplishment. Also how many covid people were returned to nursing homes in that period? How many nursing homes? Don't u see how bad this is? Or do we admit error and give up?

The recipients of this email understood—or suspected—that this was a message from Mr. Cuomo himself.[950] In a transcribed interview, Dr. Malatras testified that the demand to "[g]et a report on the facts" was referring to the July 6 Report.[951] Dr. Malatras testified that this email prompted the July 6 Report to be drafted.[952]

Dr. Zucker testified that Ms. DeRosa asked for a "medical journal" publication to be released, but the decision was made to make it a report given the pressure to release it quickly.[953] Dr. Adams testified that she viewed the NYSDOH's work on a scientific article as separate from what would eventually become the July 6 Report.[954] Dr. Adams testified that she provided "talking points" to the Executive Chamber that would be used to draft the July 6 Report.[955] According to emails, Dr. Adams sent Dr. Zucker these "talking points" within hours of the "great debacle" email.[956]

Dr. Adams also provided charts similar, but seemingly less favorable, to those that would eventually be used in the July 6 Report.[957] For example, one chart examining the average mortality rate by level of admissions and readmissions statewide showed a mortality rate of 8.1 percent for nursing homes with "[s]ome admissions or readmissions" versus a 4.1 percent mortality rate for nursing homes with "[n]o admissions or readmissions."[958]

FINDING: The July 6 Report Was Not Independently Drafted by the New York State Department of Health nor Peer Reviewed.

[950] Zucker TI, *supra* note 905, at 160-161; Transcribed Interview of Gareth Rhodes, Former Deputy Superintendent, N.Y. State Dep't of Health, *at* 104-105 (May 3, 2024) [hereinafter "Rhodes TI"]; Transcribed Interview of Jim Malatras, Ph.D., Former Advisor to the Governor, State of N.Y., *at* 130 (May 20, 2024) [hereinafter "Malatras TI"]; DeRosa TI, *supra* note 910, at 198-199.
[951] Malatras TI, *supra* note 950, at 130.
[952] *Id.* at 198.
[953] Zucker TI, *supra* note 905, at 167-168.
[954] Transcribed Interview of Eleanor Adams, M.D., Advisor, N.Y. State Dep't of Health, at 118-119 (Apr. 8, 2024) [hereinafter "Adams TI"].
[955] *Id.* at 80.
[956] E-Mail from Dr. Eleanor Adams, Special Advisor to the Commissioner, N.Y. State Dep't of Health, to Dr. Howard Zucker, Commissioner, N.Y. State Dep't of Health (June 7, 2020) (on file with Comm. Staff).
[957] *Id.*
[958] *Id*.

Dr. Adams testified that the July 6 Report was not authored by her nor the NYSDOH, and that it was not in fact a "peer reviewed" publication as claimed by Mr. Cuomo and his staff.[959] Like Dr. Adams, Dr. Malatras testified that the July 6 Report was not peer-reviewed.[960]

According to witness testimony, numerous Executive Chamber officials were involved with the July 6 Report, including Ms. DeRosa, Ms. Lacewell, Dr. Malatras, Ms. Garvey, Ms. Baldwin, and Mr. Robert Mujica—the former New York State Budget Director.[961] In response to questions related to the Executive Chamber's involvement with the July 6 Report, Ms. Lacewell testified that the report would not have existed without her.

Linda Lacewell (May 31, 2024)

Q. It reads, "The aides who were involved in change the report included Melissa DeRosa, the governor's top aide, Linda Lacewell, the head of the state's Department of Financial Services, and Jim Malatras, a former top advisor to Mr. Cuomo brought back to work on the pandemic. None had public health expertise." You mentioned all of you being involved in the report, so I believe you would agree with the listing of your three names as being involved in the report?

A. That's not what the paragraph says. It says the aides were involved in changing the report, right? That's what it actually says.

Q. And --

A. I was involved in helping draft the report.

Q. Okay.

A. Right? The whole premise of the article is mistaken. It was not a DOH report that landed in the executive chamber and was then changed.

Q. If you were responsible for the report, why was it issued as a DOH report?

A. I didn't say I was responsible for a report.

Q. Okay. What word would you use?

A. That's really your question. I described what I did with respect to the report.

[959] Adams TI, *supra* note 954, at 128-131.
[960] Malatras TI, *supra* note 950, at 196.
[961] *See generally,* Zucker TI, *supra* note 905; Malatras TI, *supra* note 950; Garvey TI, *supra* note 918; Lacewell TI, *supra* note 920; DeRosa TI, *supra* note 910.

Q. You mentioned –

A. But I'm not McKinsey doing the data and I'm not DOH weighing in and I'm not Dr. Zucker weighing in and I'm not a statistician.

Q. But you said the report wouldn't have happened but for you?

A. Correct, and it wouldn't have happened but for McKinsey, but my point there was, I'm executive chamber. I'm executive chamber. The DOH report wouldn't exist without me…[962]

Dr. Malatras testified that Ms. DeRosa was "very active" with the July 6 Report and directed what points she wanted the report to make.

Dr. Jim Malatras (May 20, 2024)

Q. Was that the extent of [Melissa DeRosa's] involvement in the report?

A. No, she was very active, sending information; things like that. She actually at one point sent an e-mail. This was prior to that meeting, but indicative of the process. She laid out the points that she wanted to have touched upon in the report.[963]

Additionally, witnesses testified that individuals and organizations outside the government played a role in the report. including Mr. Raske, Mr. Dowling, and Dr. David Grabowski, a professor of Health Care Policy at Harvard Medical School.[964] This testimony is supported by documents.

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[962] Lacewell TI, *supra* note 920, at 63-64; *See,* J. David Goodman & Danny Hakim, *Cuomo Aides Rewrote Nursing Home Report to Hide Higher Death Toll*, THE N.Y. TIMES (Mar. 4, 2021).
[963] Malatras TI, *supra* note 950, at 161.
[964] Malatras TI, *supra* note 950, at 29, 162-163, 197; DeRosa TI, *supra* note 910, at 235.

Subject: Fw: CONFIDENTIAL
Date: Tuesday, June 30, 2020 at 4:32:24 PM Eastern Daylight Time
From: [redacted]
To: [redacted]

From: Dowling, Michael [redacted]
Sent: Tuesday, June 30, 2020 4:31 PM
To: [redacted]
Subject: CONFIDENTIAL

[redacted]

Overall – a good document. A few suggestions, however:

1. The Exec Summary needs to be redone with a clear statement of the problem/issue and the conclusion. That is, in effect, your press release. I would suggest something like the following.

   There has been much discussion of the number of nursing home patient deaths in NY and the causal relationship between nursing home admission policy and resident mortality. The DOH completed an independent analysis etc. and concluded:

   - NY State has a lower percentage of deaths in nursing homes than most states – ranking 46th.
   - Admission policies were not the factor in nursing home fatalities.
   - Mortality rate transmission is strongly correlated to employees entering the facilities.

   Ken Raske's staff and mine can do a complete rewrite if you wish.

2. Don't overly rush to get this out – not until there is a rewrite. It will get criticized and opponents will argue – even if they buy the argument – that we should have done more earlier to test the staff. This is political.

3. I am working with Ken to line up some physicians to be available to support the Commissioner – this will take a day or so.

I am waiting for my physician to get back to me. She is reviewing the report. Once I do, I will follow up with you.

Michael

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Subject: Fw: [EXTERNAL] Fwd: Revised Executive Summary
Date: Wednesday, July 1, 2020 at 8:18:33 AM Eastern Daylight Time
From: [redacted]
To: [redacted]
Attachments: 06302020 Nursing Home Report V14 Tuesday.docx, ATT00001.htm

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From: Dowling, Michael [redacted]
Sent: Tuesday, June 30, 2020 8:42 PM
To: [redacted]
Subject: Fwd: [EXTERNAL] Fwd: Revised Executive Summary

Sent from my iPhone

Begin forwarded message:

> **From:** "Raske, Ken" [redacted]
> **Date:** June 30, 2020 at 6:00:02 PM EDT
> **To:** "Dowling, Michael" [redacted]
> **Subject: [EXTERNAL] Fwd: Revised Executive Summary**
>
> ***External Email. Use Caution.***
> Per our discussion. Ken
>
> Sent from my iPad
>
> Begin forwarded message:
>
> > **From:** "Conway, Brian" [redacted]
> > **To:** "Raske, Ken" [redacted]
> > **Subject: Revised Executive Summary**
> >
> > Ken, a revised draft Executive Summary is below.
> >
> > The entire draft paper, including the original Executive Summary, is attached.

In response to an article by *The New York Times* reporting the Executive Chamber's involvement in the July 6 Report,[965] Dr. Malatras issued a statement saying that he was not involved in altering the nursing home numbers.[966] Thereafter, Dr. Malatras testified that he received a call from Executive Chamber Officials, including Ms. DeRosa, Ms. Lacewell, Ms. Garvey, and others, asking him to "put out a statement suggesting otherwise" because they

[965] J. David Goodman & Danny Hakim, *supra* note 962.
[966] *See,* Bernadette Hogan & Bruce Golding, *Cuomo official Malatras appears to throw cohorts under bus in nursing home denial*, N.Y. POST (Mar. 5, 2021).

believed *The New York Times* reporting and his statement to be misleading.[967] Dr. Malatras refused.[968]

FINDING:	Mr. Andrew Cuomo Reviewed and Edited the July 6 Report, and His Edits Were to Make the Report's Findings More Causal.

Mr. Cuomo testified that he did not have any involvement with the drafting of the July 6 Report. He further stated that he did not recall reviewing or editing the July 6 Report.[969]

Mr. Andrew Cuomo (June 11, 2024)

Q. Were you involved in the drafting of this report in any capacity?

A. No.

Mr. Andrew Cuomo (June 11, 2024)

Q. In the minority hour, did you testify that you had no role in the July 6 Report?

A. I do not recall seeing the July 6 report prior its issuance. It was Howard Zucker's report. He then presented it numerous times. I then spoke to it numerous times, because it came up at every press briefing afterwards.

Q. And to clarify your testimony, you did not recall reviewing the report?

A. I do not recall reviewing.

Q. Did you edit the report?

A. I don't recall seeing it.

However, Mr. Cuomo's testimony is directly contradicted by documents and other witness testimony. It is also contradicted by the report entitled, "Impeachment Investigation Report to Judiciary Committee Chair Charles Levine and the New York State Assembly Judiciary Committee" [hereinafter "Impeachment Report"].[970] Dr. Malatras testified that Mr. Cuomo

[967] Malatras TI, *supra* note 950, at 212-214; Lacewell TI, *supra* note 920, at 63-64.
[968] Malatras TI, *supra* note 950, at 212-214; Lacewell TI, *supra* note 920, at 63-64.
[969] Cuomo TI, *supra* note 907, at 173. 285-286.
[970] Impeachment Investigation Report to Judiciary Committee Chair Charles Levine and the New York State Assembly Judiciary Committee, at 40, Davis Polk & Wardwell LLP (Nov. 22, 2021) [hereinafter "Impeachment Report"] ("[T]he evidence obtained in our investigation demonstrates that former Governor Cuomo directed officials from the Executive Chamber, Task Force and DOH to prepare a report from DOH in order to combat criticism of the March 25 Directive. The report was initiated by the then-Governor and influenced by members of the Executive

reviewed and edited the July 6 Report.[971] Dr. Malatras also testified that the former Governor would have had final approval on the report.[972]

When Select Subcommittee counsel informed Mr. Cuomo that Dr. Malatras had testified that the former governor was involved in reviewing the July 6 Report, he again denied involvement.

> **Mr. Andrew Cuomo (June 11, 2024)**
>
> Q. Dr. Malatras also told us in his testimony that you did review a draft of this report prior to its release. Is that true?
>
> A. I did not. Maybe it was in the inbox, but I did not.[973]

Documents and testimony, however, show that Mr. Cuomo was intimately involved in the review and drafting of the report.

Subject: RE: on track for noon?
Date: Monday, June 22, 2020 at 12:29:51 PM Eastern Daylight Time
From: [redacted]
To: [redacted]

Can you shoot over? He's asking

From: [redacted]
Sent: Monday, June 22, 2020 11:55 AM
To: [redacted]
Subject: Re: on track for noon?

I will get you what I have. Howard's people will need to fill in section and McKinsey isn't done yet, but I will get you where it is.

From: [redacted]
Date: Monday, June 22, 2020 at 11:54 AM
To: [redacted]
Subject: on track for noon?

Chamber and Task Force, then released under the auspices of DOH. Throughout the drafting process, the former Governor reviewed and edited the draft DOH Report on multiple occasions and made edits to strengthen the defense of the March 25 Directive.").

[971] Malatras TI, *supra* note 950, at 207-208.

[972] *Id.* at 165.

[973] Cuomo TI, *supra* note 907, at 177.

Subject: edits
Date: Monday, June 29, 2020 at 5:09:32 PM Eastern Daylight Time
From: [redacted]
To: [redacted]
Attachments: nursing homes report v10 MONDAY.docx

Can you make the change to the first sentence and send back for me to show him? I can't figure out how to finesse it
(can you also do a read through of the edits and make sure you agree?)

Subject: Re: 06.23.20 Nursing Homes 230PM.docx
Date: Wednesday, June 24, 2020 at 7:58:04 AM Eastern Daylight Time
From: [redacted]
To: [redacted]
CC: [redacted]

farrah/tracy pls have copies printed for gov and i to take on plane this morning

---

From: [redacted]
Sent: Wednesday, June 24, 2020 12:11 AM
To: [redacted]
Cc: [redacted]
Subject: Re: 06.23.20 Nursing Homes 230PM.docx

Attached are the Governor's edits as well as my edits. I've reformatted & charts have been re-added. I will want to read through with fresh eyes tomorrow.

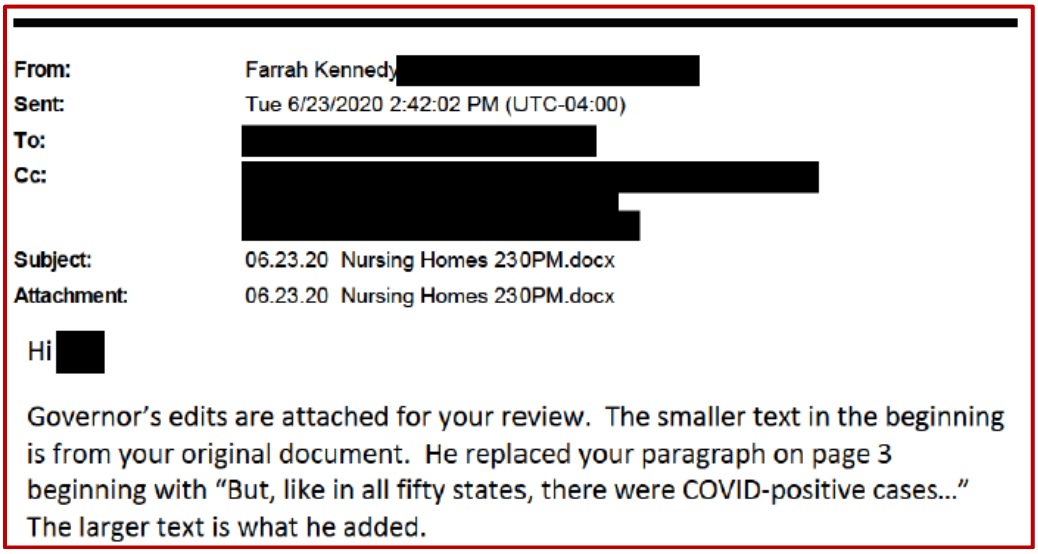
Subject: [redacted] - how much longer on NH report? He's asking for copy
Date: Sunday, July 5, 2020 at 8:53:52 AM Eastern Daylight Time
From: [redacted]
To: [redacted]
CC: [redacted]

Subject: Re: Privileged and confidential
Date: Sunday, July 5, 2020 at 6:01:49 PM Eastern Daylight Time
From: [redacted]
To: [redacted]
CC: [redacted], Will Burns, Noah Rayman, Richard Azzopardi, Gareth Rhodes (dfs.ny.gov)

did we make the change boss sent w the specific quote from the regs/advisory on what was required?

Dr. Malatras further testified that Mr. Cuomo would edit the July 6 Report via handwritten notes or via Mr. Cuomo's assistants and that Mr. Cuomo edited the language of the July 6 Report to be more causal.[974] Dr. Malatras' testimony is confirmed by documents.

On June 23, 2020, Ms. Kennedy emailed Executive Chamber staff an attachment with the "Governor's edits."[975]



From: Farrah Kennedy [redacted]
Sent: Tue 6/23/2020 2:42:02 PM (UTC-04:00)
To: [redacted]
Cc: [redacted]
Subject: 06.23.20 Nursing Homes 230PM.docx
Attachment: 06.23.20 Nursing Homes 230PM.docx

Hi [redacted]

Governor's edits are attached for your review. The smaller text in the beginning is from your original document. He replaced your paragraph on page 3 beginning with "But, like in all fifty states, there were COVID-positive cases..." The larger text is what he added.

In a transcribed interview, Ms. Kennedy testified that she was communicating edits from Mr. Cuomo.[976] Furthermore, Ms. Kennedy testified that she understood Mr. Cuomo's edits to be identified in larger text that consisted of more than 10 pages.[977] A text message contemporaneous to Mr. Cuomo's edits, suggests that NYSDOH staff were concerned that Mr. Cuomo's edits to the July 6 Report "may not be scientifically accurate."

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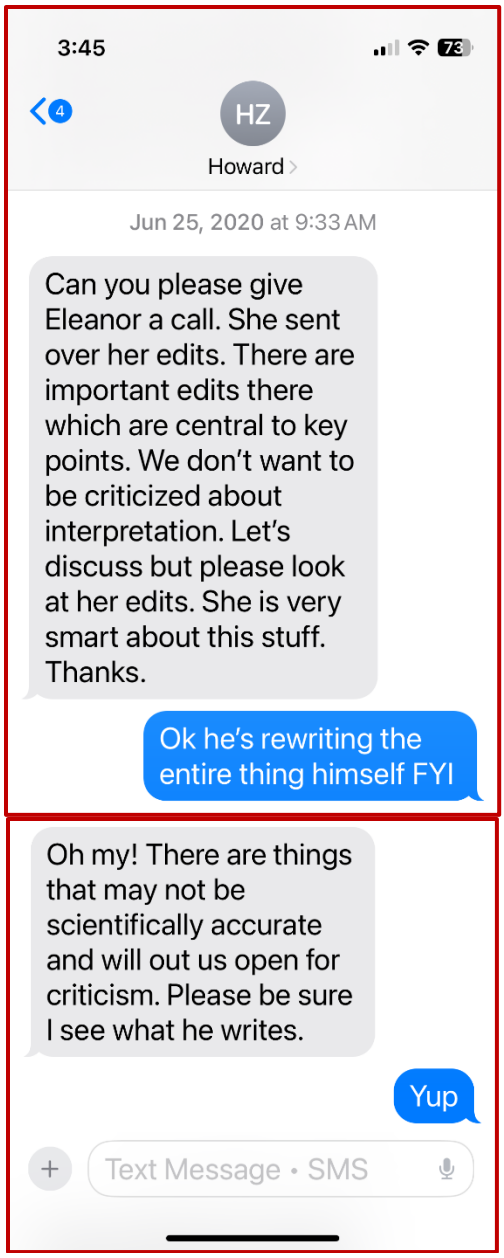
[974] Malatras TI, *supra* note 950, 208-209
[975] E-Mail from Farrah Kennedy, Executive Assistant, Executive Chamber, N.Y., to Executive Chamber Staff (June 23, 2020, 2:42 PM.).
[976] Transcribed Interview of Farrah Kennedy, Executive Assistant, N.Y. Executive Chamber, 20-21 (Oct. 8, 2024) [hereinafter "Kennedy TI"].
[977] *Id.*


3:45
HZ
Howard
Jun 25, 2020 at 9:33 AM
Can you please give Eleanor a call. She sent over her edits. There are important edits there which are central to key points. We don't want to be criticized about interpretation. Let's discuss but please look at her edits. She is very smart about this stuff. Thanks.
Ok he's rewriting the entire thing himself FYI
Oh my! There are things that may not be scientifically accurate and will out us open for criticism. Please be sure I see what he writes.
Yup
Text Message • SMS

On June 24, 2020, a scanned version of the July 6 Report was sent to Executive Chamber staff.[978] The scanned version of the July 6 Report included handwritten edits and comments.[979]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[978] E-Mail from Executive Chamber Staff to Executive Chamber Staff (June 24, 2020, 10:55 AM).
[979] *Id.*

Subject: Fwd: Message from "RNP58387911B637"
Date: Wednesday, June 24, 2020 at 11:13:44 AM Eastern Daylight Time
From: [redacted]
To: [redacted]
Attachments: 20200624105333189.pdf, ATT00001.htm

Privileged
Can you read this?

Sent from my iPhone

Begin forwarded message:

From: [redacted]
Date: June 24, 2020 at 10:55:15 AM EDT
To: [redacted]
Subject: FW: Message from "RNP58387911B637"

-----Original Message-----
From: Ricoh39Copier1@exec.ny.gov [mailto:Ricoh39Copier1@exec.ny.gov]
Sent: Wednesday, June 24, 2020 10:54 AM
To: [redacted]
Subject: Message from "RNP58387911B637"

This E-mail was sent from "RNP58387911B637" (MP C6004ex).

Scan Date: 06.24.2020 10:53:33 (-0400)
Queries to: Ricoh39Copier1@exec.ny.gov

Ms. Kennedy testified that part of her responsibilities as Executive Assistant to the Governor were to transcribe Mr. Cuomo's handwritten notes.[980] When asked to review the handwritten notes of the draft from June 24, 2020, Ms. Kennedy testified that it appeared to be Mr. Cuomo's handwriting.[981] Below is an example of Mr. Cuomo's handwritten edits to the June 24, 2020 draft of the July 6 Report.

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[980] Kennedy TI, *supra* note 976, at 24-25.
[981] *Id.* at 25.

the March 7, 2020 federal CDC guidance further stated, "Facilities could consider allowing asymptomatic HCP who have had an exposure to a COVID-19 patient to continue to work after options to improve staffing have been exhausted and in consultation with their occupational health program."[5] Therefore, asymptomatic nursing home employees may not have been detected.

In early March the nation's testing capacity was still being developed and was not widely available for nursing home employees. Yet, for nursing home employees that were symptomatic, but not tested, CDC recommended that they wait only three days after the symptoms had passed to return to work and only seven days after the COVID-19-like symptoms first appeared, much less time than the 14 days required under certain circumstances.[6] It is likely that a percentage of these symptomatic employees could have spread the disease within the facility.

The peak of nursing home fatalities was at the beginning of April. Given the incubation period for COVID-19 as a median time of 4-5 days from exposure to symptoms onset, and can extend to 14 days, it is likely that employees infected in mid-March could have appeared in the nursing home for work, transmitted the virus which then manifested in the residents approximately 7-14 days later. As Figure 2 illustrates, peak in COVID-symptomatic nursing homes employees was in mid-March is potentially correlated to peak nursing home deaths in the first week in April.

Control and Prevention (March 7, 2020) located at https://web.archive.org/web/20200404194131/https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html.

[5] Id.

[6] "Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19 (Interim Guidance)" Centers for Disease Control and Prevention located at: https://web.archive.org/web/20200404023742/https:/www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhealthcare-facilities%2Fhcp-return-work.html.

8

On June 28, 2020, Executive Chamber staff communicated about more of Mr. Cuomo's edits to the July 6 Report.[982]

[982] E-Mail from Executive Chamber Staff to Executive Chamber Staff (June 28, 2020, 3:20 PM).

Subject: RE: edits to Nursing Home doc
Date: Sunday, June 28, 2020 at 3:20:56 PM Eastern Daylight Time
From: [redacted]
To: [redacted]
CC: [redacted]
Attachments: nursinghomedoc-govedits.pdf

Upon closer inspection they aren't edits I can make. Attached are the Governor's edits. [redacted] – I believe [redacted] has the most recent word version.

Thanks.

From: [redacted]
Sent: Sunday, June 28, 2020 3:04 PM
To: [redacted]
Cc: [redacted]
Subject: edits to Nursing Home doc

[redacted] – the Governor handed over edits to the version you asked me to give to him. If you send me the document – I can make the edits and send back to all. Thanks.

The version of the July 6 Report attached to this e-mail also included handwritten edits and comments. When asked about source of the handwriting, Ms. Kennedy testified that it appeared to be Mr. Cuomo's handwriting.[983] Below is an example of Mr. Cuomo's handwritten edits to the June 24, 2020 draft of the July 6 Report.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[983] Kennedy TI, *supra* note 976, at 26.

43	District of Columbia	20	1,072	173	32%
44	Wyoming	4	54	6	30%
45	Nevada	75	1,289	135	27%
46	New York	509	7,177	6,432	21%
47	Alabama	131	3,746	112	—
48	Hawaii	15	89	1	—
49	Missouri	118	1,394	15	—
50	Alaska	10	93	0	—
51	Wisconsin	318	1,242	0	—

SOURCE: *New York Times;* States with insufficient data to calculate a share of Covid-19 deaths are shaded gray.

Further, an examination of fatalities in our neighboring states – despite having populations much smaller than New York's –illustrates clearly that nursing home fatalities were not a New York specific phenomenon: New Jersey reports 6,617 nursing home deaths, Massachusetts reports 5,115 nursing home deaths, Pennsylvania reports 4,518 nursing home deaths and Connecticut reports 3,124, compared to New York's XX

II. COVID-19 Staff Illness Contributed to Infections of Nursing Home Residents

Within New York State, there has been significant geographic variation in overall positive tests within the community (Figure 1) and nursing home cases and fatalities. The most impacted regions in New York State were in the downstate region (Mid-Hudson Valley, New York City, and Long Island) and those regions had the highest nursing home fatality rates.

This is a higher need area

Accordingly, Ms. Kennedy testified that Mr. Cuomo was involved in the drafting of the July 6 Report.[984]

FINDING:	Mr. Andrew Cuomo Was Involved in the "Peer Review" Process and Directed Individuals Outside of New York State Government to Review the July 6 Report.

Documents and testimony establish that Mr. Cuomo was involved in directing an external "peer review" process of the July 6 Report. Mr. Cuomo denied having any involvement in peer-review process.

Mr. Andrew Cuomo (June 11, 2024)

Q. Did you have any discussions regarding the report being peer reviewed?

A. No.[985]

Mr. Cuomo testified that he did not know whether any individual outside of NYSDOH was involved in the drafting or editing of the July 6 Report.

Mr. Andrew Cuomo (June 11, 2024)

Q. Do you know if people outside of DOH were involved with drafting or editing this report?

A. No.[986]

Dr. Malatras testified to the Select Subcommittee that individuals outside the NYSDOH, including Mr. Dowling and Mr. Raske, President were involved.[987]

Documents show that Mr. Cuomo directed the July 6 Report be peer reviewed by Mr. Dowling and Mr. Raske. On June 30, 2020, Ms. Benton emailed Executive Chamber staff. A former Executive Chamber staffer told the Select Subcommittee this e-mail was likely from Mr. Cuomo, consistent with his practice of dictating emails Ms. Benton sent. The email directed, "[g]et that Harvard guy[,] dowling[,] and ken Davis [sic] to be the 'peer review' experts of the report. Get them the draft now to study."[988]

[984] Kennedy TI, *supra* note 976, at 26.
[985] Cuomo TI, *supra* note 907, at 287.
[986] *Id.* at 173.
[987] Malatras TI, *supra* note 950, at 29.
[988] E-Mail from Stephanie Benton to Executive Chamber Staff (June 30, 2020, 10:59 AM).

Subject: Ok?
Date: Tuesday, June 30, 2020 at 10:59:30 AM Eastern Daylight Time
From: Stephanie Benton
To: [redacted], [redacted] (health.ny.gov), [redacted], [redacted]

."we need to get the nursing home report out tomm morn at a 9 30 briefing in the city. Get the Harvard guy dowling and ken Davis to be the "peer review" experts of the report. Get them the draft now to study. They need to know the facts. Melissa do a briefing session with them tonite and walk thru report. Dr zucker has to know the report cold an be an aggressive advocate. The others will key off him. No one will be more aggressive than u Dr zucker. If they see u defer they will too. U have to set the tone. The facts are powerful. Giving these guys one day notice is unfair so get them the draft asap and walk them thru it.
Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

The e-mail does not specify who "dowling" and "ken" are, but subsequent e-mails establish that Mr. Cuomo meant Mr. Dowling and Mr. Raske. Later that same day, Mr. Dowling sent back edits and suggestions to an Executive Chamber staff.[989] Mr. Dowling even stated, "Ken Raske's staff and mine can do a complete rewrite [of the Executive Summary] if you wish."[990] That evening, Mr. Raske sent his edits to Mr. Dowling, who then forwarded them to the Executive Chamber.[991]

Accordingly, these documents and testimony establish that Mr. Cuomo had conversations regarding the "peer review" of the July 6 Report and directed and knew that people outside of the NYSDOH were involved in the July 6 Report.

FINDING:	The Executive Chamber Decided to Remove Out-of-Facility Death Data from the July 6 Report.

Dr. Adams testified that the original NYSDOH analysis—that was going to be a scientific paper—included both in-facility and out-of-facility nursing home fatalities.

Dr. Eleanor Adams (April 8, 2024)

Q. …[W]ould that number [of out-of-facility deaths] have been in the scientific report you working on?

A. Yes. In our draft – well, I should rephrase. I'm not sure if this answers your questions but in our draft paper, we included the numbers of in and out of nursing home, deaths of nursing home residents…[992]

[989] E-Mail from Michael Dowling, Chief Exec. Office, Northwell Health, to Executive Chamber Staff (June 30, 2020), 4:31 PM).
[990] *Id.*
[991] E-Mail from Kenneth Raske, Pres. & Chief Exec. Officer, Greater N.Y. Hospital Ass'n, to Michael Dowling, Chief Exec. Officer, Northwell Health (June 30, 2020, 6:00 PM).
[992] Adams TI, *supra* note 954, at 98.

According to witness testimony, the initial drafts of the report analyzed in-facility and out-of-facility nursing home deaths.[993] Accordingly, the initial drafts of the report cited the total nursing home deaths as approximately 10,000.

Dr. Malatras testified that the decision to not include out-of-facility deaths occurred on a phone call on June 27, 2020.

Dr. Jim Malatras (May 20, 2024)

Q. Who was on that call?

A. It was – I believe it was me, Beth Garvey, Linda Lacewell, Howard Zucker, Melissa DeRosa, and there could have been some others. I don't know. . .

Q. Why was that call called?

A. It was about the nursing home report. [994]

Further, Dr. Malatras testified that the decision was made after Ms. DeRosa "aggressively" questioned Dr. Zucker on out-of-facility death data.

Dr. Jim Malatras (May 20, 2024)

Q. You mentioned earlier a call on June 27th, I believe, with Ms. DeRosa and a variety of other people about the numbers going into the report. And you said Ms. DeRosa made some demands related to those numbers. If we could just reiterate what she said on that call?

A. The call in question was the data that we were provided from McKinsey, that she forwarded to us after that initial e-mail from Stephanie Benton, or Governor Cuomo through Stephanie Benton. It had a whole bunch of data in it, and including the curves and everything like that in the charts; that included the full in-the-facilities health care – in the hospitals and in the nursing home facilities with fatalities. That continued to be the report through all of those charts, through the June 27th call. I don't know what precipitated the change in Ms. DeRosa – something happened. She talked to somebody. Something triggered a response, which she then called a meeting, and was very aggressive about questioning the numbers, why those numbers. Mostly aimed at Dr. Zucker, but we were – none of us were immune from the – I would say – passionate

[993] Malatras TI, *supra* note 950, at 160-161; Lacewell TI, *supra* note 920, at 115; Garvey TI, *supra* note 918, at 163.
[994] Malatras TI, *supra* note 950, at 106-107.

interaction. And then, thereafter, she said she does not trust the numbers. She wants it to be continually be – the numbers that were publicly reported until, you know, they could do a review on the numbers.[995]

Dr. Malatras testified it was Ms. DeRosa's decision to not include out-of-facility nursing home fatalities.[996] He testified that he believed out-of-facility death data should have been included in the report.

Dr. Jim Malatras (May 20, 2024)

Q. Do you believe those numbers should have been included in the report?

A. I would have – if I had the authority to do so, I would have included them, again, so that we wouldn't be sitting together right now.

Q. Was that discussed among the people who were working on editing the report?

A. Most people thought the numbers should be out, and that was – should be the end of it. That's why they were in the report until the June – they were in the – all the charts had these numbers until June 27th.

Q. You talked about being directed by Ms. DeRosa to make that change. Did anyone else agree with her –

A. No.

Q. --or was it just she's the top of the chain, I'm going to listen?

A. Well, Mr. Zucker – if I remember the call correctly – was trying to push back a little bit. I think at one point, Ms. Garvey did. There was some ire turned my way about it, but there – sometimes, as you know with the principal, there's not – there's certain discussions – certain decisions made of which you don't – they have ultimate authority and that was that.

Q. Sure.

A. I followed up with an e-mail afterwards because I was frustrated.

Q. An e-mail saying that you thought –

[995] *Id.*
[996] *Id*. at 106, 206.

A. No, let me share this. I was the one in the impeachment report that said no one should have been shocked or surprised by the 10,000 number. You guys gave me – the report with those numbers came from you. We synthesized the information in the report. We gave you the report, and now you are criticizing us for things that you gave us. So I was frustrated at that moment very much so. And I was frustrated by the tone on the call very much so. We were all pretty exhausted by that point…[997]

However, Ms. DeRosa testified that it was Dr Zucker's decision to remove out-of-facility nursing home deaths. Dr. Zucker testified that he stood by the findings of the July 6 Report.[998]

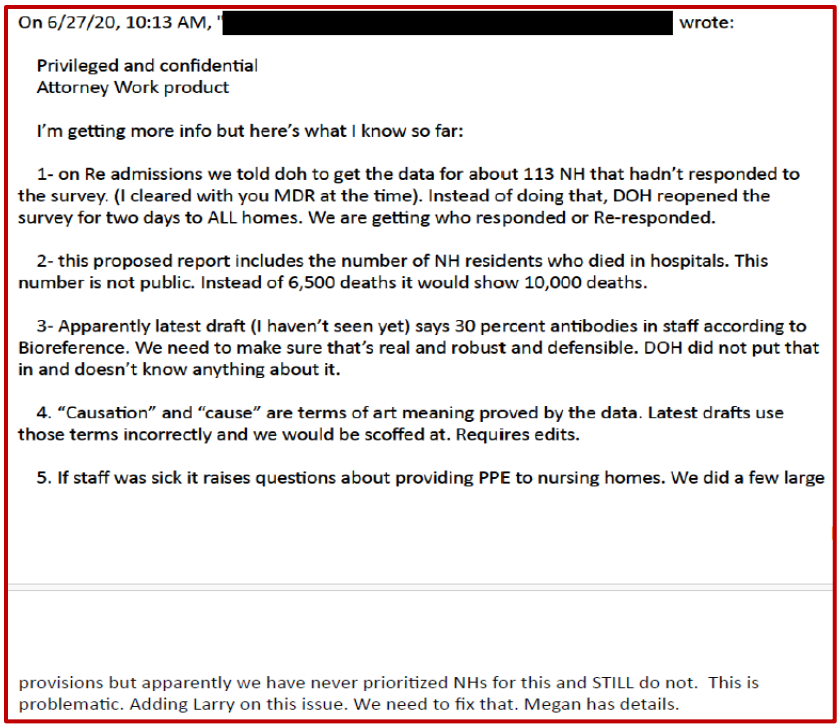
Ms. Melissa DeRosa (June 23, 2024)

Q. Is the penultimate conversation the June 27th phone call?

A. I don't know the actual date, but there was that conversation which was like the big group conversation which has been reported and discussed previously. But the questions to DOH not just from me, but from others including Linda. Including Beth, including other people, that were looking at this report, because it, was data that had never been previously published was, has this been vetted or verified? No. In looking at the cursory numbers, we've all agreed previously that this information has to be audited because it's incorrect. Has anything changed? No. Have you done anything to figure out which information is incorrect? No. How certain are you of the numbers that are reported from outside facilities that they are correct? Silence. Are you seriously proposing using numbers in a report to back a conclusion that the March 25th guidance didn't influence bringing COVID into nursing homes, knowing that the numbers are wrong? Not thinking that they could be wrong but knowing that they're wrong? Silence. What do we want to do here, guys? What do you want to do here? And Zucker said, it doesn't alter the conclusion, the ultimate conclusion is the same, so let's use the vetted verified numbers, be clear that's what we're doing and we will audit them later. And so it was Zucker's call. Zucker had to defend it, Zucker had to put his name on it. As Zucker told the Assembly, if he disagreed with it, he would not say it out loud. His name was one it. It was his call…[999]

[997] *Id.* at 168-169.
[998] Zucker TI, *supra* note 905, at 200.
[999] DeRosa TI, *supra* note 910, at 245.

Prior to the phone call, Ms. Lacewell emailed Executive Chamber staff that the out-of-facility fatality data was not public.[1000] Ms. Lacewell also highlighted other concerns related to other sections of the report—including that New York was not prioritizing nursing homes for PPE.[1001]



On 6/27/20, 10:13 AM, '[redacted] wrote:

Privileged and confidential
Attorney Work product

I'm getting more info but here's what I know so far:

1- on Re admissions we told doh to get the data for about 113 NH that hadn't responded to the survey. (I cleared with you MDR at the time). Instead of doing that, DOH reopened the survey for two days to ALL homes. We are getting who responded or Re-responded.

2- this proposed report includes the number of NH residents who died in hospitals. This number is not public. Instead of 6,500 deaths it would show 10,000 deaths.

3- Apparently latest draft (I haven't seen yet) says 30 percent antibodies in staff according to Bioreference. We need to make sure that's real and robust and defensible. DOH did not put that in and doesn't know anything about it.

4. "Causation" and "cause" are terms of art meaning proved by the data. Latest drafts use those terms incorrectly and we would be scoffed at. Requires edits.

5. If staff was sick it raises questions about providing PPE to nursing homes. We did a few large

provisions but apparently we have never prioritized NHs for this and STILL do not. This is problematic. Adding Larry on this issue. We need to fix that. Megan has details.

Dr. Malatras responded, a response previously reported in part in the Impeachment Report, to Ms. Lacewell's email to express his concerns with not including out-of-facility fatalities in the July 6 Report.[1002]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1000] E-Mail from Executive Chamber Staff to Executive Chamber Staff (June 27, 2020, 10:13 AM).
[1001] *Id.*
[1002] E-Mail from Executive Chamber Staff to Executive Chamber Staff, N.Y. State (June 27, 2020, 10:58 AM).

Subject: Re: NH report
Date: Saturday, June 27, 2020 at 10:58:23 AM Eastern Daylight Time
From: [redacted]
To: [redacted]

Attachments: image001.png

And just so there is clarity here. The 10,000 deaths number should not be a surprise, shock, or anything to folks. It came from earlier drafts and analysis provide from you all to me that you worked on with McKinsey. On the briefing call going thru this data it was stated we needed to use the presumed and confirmed or the curve wouldn't work for the broader community spread argument, given testing was spotty at the beginning. I'm happy to remove that argument, which came from folks.

Below is the chart from the original McKinsey deck and was in the original draft provided by NYSDOH.

New York State's nursing homes population had an above average morta
it also represented a lower share of Statewide fatalities than in most oth

State	Statewide confirmed fatalities[1]	Date of first death	Average facility size	Total nursing homes/LTC fatalities	Of which confirmed fatalities	Delta in fatalities for 2020 (less COVID conf.)[4]	Statewide fatalities p 100k population
New Jersey[2]	12,303	11-Mar	119	6,172		4,356	
New York[2]	24,348	15-Mar	169	9,250	5,832	2,968	
Connecticut[2]	4,097	19-Mar	103	2,542	2,015	415	
Massachusetts	7,408	18-Mar	99	4,630		1,128	
Louisiana[2]	2,944	15-Mar	94	1,223		836	63.3
Michigan[3]	5,943	19-Mar	86		2,297	2,728	59.5
Illinois	6,018	17-Mar	91	3,144		2,513	47.5
Maryland	2,844	18-Mar	105		1,368	1,169	47.0
Pennsylvania	6,014	18-Mar	109		4,117	4,691	47.0
Indiana	2,158	16-Mar	73	1,011		585	32.1
Colorado[2]	1,553	14-Mar	74	482	370	608	27.0
Minnesota	1,217	21-Mar	65		968	171	21.6
Georgia	2,285	13-Mar	93	1,119		866	21.5
Ohio	2,421	20-Mar	75		1,272	769	20.7
Virginia	1,514	15-Mar	98		845	1,069	17.7
Washington[3]	1,176	26-Feb	75		34	66	15.4
Arizona[3]	1,070	21-Mar	81		129	679	14.7
Florida	2,765	11-Mar	106	1,332		953	12.9
California[2]	4,697	12-Mar	87	2,003		2,230	11.9
North Carolina	1,029	25-Mar	86		544	171	9.8
Texas[2]	1,853	17-Mar	77		751	2,972	6.4

1. States with less than 1,000 confirmed state-wide fatalities were not included in this state comparison
2. Includes nursing home fatalities from hospital and facilities only (not other LTC facilities)
3. Number of confirmed nursing home deaths reported to CMS
4. Delta in deaths associated with COVID-19 reported by CDC (less COVID confirmed deaths)

SOURCE: DOH by state estimates

Preliminary, proprietary, and pre-decisional. Any use of this material with

A subsequent response from Ms. Lacewell confirmed that the June 27 phone call, where the decision was made to remove out-of-facility deaths, was in response to a question posed by Ms. DeRosa. While Ms. Lacewell stated that "a [questions] from MDR" and "reason for" the June 27 phone call, it is unclear Ms. DeRosa asked because the Executive Chamber invoked attorney client privilege.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

Subject: Re: NH report
Date: Saturday, June 27, 2020 at 11:00:36 AM Eastern Daylight Time
From: [redacted]
To: [redacted]
Attachments: image001.png

It was a q from MDR and reason for this morning's call.

Sent from my iPhone

Furthermore, the Select Subcommittee is aware of additional communications regarding the June 27 call. However, as of December 4, 2024, the Executive Chamber has yet to produce them.

In response to questions related to the Executive Chamber's decision to remove out-of-facility deaths from the July 6 Report, Mr. Cuomo remarked "[w]ho cares."

Mr. Andrew Cuomo (June 11, 2024)

Q. Do you – and Ms. Lacewell confirmed this as well, that drafts of the report before the phone call had the 9,844 number in it, and drafts of the report after the phone call had 6,432. Do you recall any conversations about that?

A. No, but I don't know how to express – let's say there's a 3,000 differential, 2,500. Who cares? What difference does it make in any dimension to anyone about anything? Do you know what I'm saying?[1003]

FINDING: The New York Executive Chamber Made the Decision to Not Publicly Report Out-of-Facility Deaths.

Dr. Malatras testified that Ms. DeRosa made the decision to change the methodologies in which nursing home fatalities were publicly accounted for and reported.[1004]

Dr. Jim Malatras (May 20, 2024)

Q. But to be clear, what you're testifying is that Melissa DeRosa was involved in the decision to change the methodology that was used throughout the pandemic?

[1003] Cuomo TI, *supra* note 907, at 289.
[1004] Malatras TI, *supra* note 950, at 143-144.

A. It was her decision.

Dr. Malatras testified that Ms. DeRosa did not "trust the numbers" related to reporting out-of-facility fatalities and made the decision to exclude them.[1005] Similarly, Ms. DeRosa testified that the out-of-facility "numbers were wrong."

Dr. Jim Malatras (May 20, 2024)

Q. … Do you know what necessitated the administration making this change?

A. This is a question of location?

Q. Yes.

A. Yeah, this is – this is the same issue. My understanding was even after the audit – I don't know. You have to ask them about why they didn't do it after the audit. But prior to the audit conducted by Gareth Rhodes, Ms. DeRosa said she didn't trust the numbers.

Q. …This decision to change the methodology to exclude nursing home deaths would have been approved by Ms. DeRosa?

A. Correct.[1006]

According to witness testimony, the Executive Chamber was advised by numerous officials to release the full accounting of nursing home fatalities. Mr. Rhodes testified that he was ordered by Ms. DeRosa to conduct an audit of NYSDOH data following a hearing in August 2020.[1007] Mr. Rhodes testified that Ms. DeRosa was concerned with double counting.

Mr. Gareth Rhodes (May 3, 2024)

Q. But isn't it true . . . that after this hearing you were ordered to conduct an audit of the Department of Health's data?

A. I recall it like a common sense review of a data set that I was asked to, you know, go over and sit down with their staff and go through it line by line and make sure there were no discrepancies or any inconsistencies.

Q. …[W]ho ordered you to conduct this audit?

A. Melissa asked me to go over there and do this review.

[1005] *Id.* at 147.
[1006] DeRosa TI, *supra* note 910, at 55.
[1007] Rhodes TI, *supra* note 950, at 116-117.

Q. Did she explain why?

A. I don't recall really the conversation, just, you know, can you – what – you know, do you mind going there and taking a look at this. I think there was – I think she – I remember she mentioning like double-counting or like she wanted me to make sure that the numbers didn't have inaccuracies or inconsistencies.[1008]

Mr. Rhodes testified that it took no longer than a week to complete his audit of the nursing home fatality data and that he flagged "maybe 600" entries as "inconsistent."

Mr. Gareth Rhodes (May 3, 2024)

Q. ... [C]an you just provide a general summary of what you found?

A. To the best of my recollection, this was some time ago, there was like an Excel spreadsheet on a DOH computer. For every fatality there was like a line that had like the initials, it had the facility, it had date of admission, date of death, like the comorbidities. I had like – like ran some like Excel formulas. Was really looking to see is there anything here like – I am not a data scientist. I was more looking at this like a commonsense kind of approach. And I was looking for things like – you know, anything that looked inconsistent. And I think I flagged maybe 600 or so entries that had some sort of thing that could be considered inconsistent. Like someone had been marked as having passed away like before they had been admitted. There were like some cases of people who were confirmed to have died of COVID before COVID had been reported in New York.[1009]

Mr. Rhodes identified himself as the Task Force member in the Impeachment Report that advised the Executive Chamber to release the full data set.[1010] Mr. Rhodes testified that he believed his audit to be sufficient and believed that the full data set should have been released with a disclaimer related to the inconsistencies.

Mr. Gareth Rhodes (May 3, 2024)

Q. But for the record, you are testifying today that you did support releasing the numbers in August of 2020?

A. Yes.

[1008] *Id.*
[1009] *Id.* at 118-119.
[1010] *Id.* at 121.

Q. And do you recall why you supported releasing the numbers?

A. In my view – as part of my kind of review of these numbers, I thought maybe my review, you know, was – you know, I thought I had done my job. I found kind of any discrepancies, I identified them. We could – Department of Health could maybe follow up on the discrepancies and that would be – you know, if there were any concerns, you know, about the inconsistencies like maybe my review had helped resolve those, I was not sure, but like at least maybe provided some – some input or helpfulness on that side. And that – you know, there's mention here about the legislature had written a letter requesting the numbers and, you know, I thought that it made sense to put those – put the numbers in that letter and then maybe add an asterisk that said, you know, review had found maybe there were 600 that were continued to be follow up on. Those – just as a note that those were being validated. That's what I thought just made sense based on what my review was.[1011]

Similarly, Dr. Zucker testified that he was the Senior NYSDOH Official in the Impeachment Report that prepared a letter in August 2020 that reported the full number of nursing home fatalities to the legislature.[1012] He testified that he also prepared a second letter in October 2020 that was never approved.

Dr. Howard Zucker (December 18, 2023)

Q. So based on the Impeachment Report, does it follow that there were nursing home numbers that included residents that were transferred to the hospital that the Executive chose not to release in August of 2020?

A. But the numbers – I'm unclear. I'm unclear what the question is. What I'm reading here says that the letter that we put together, which had all the numbers, and it did not go back to the legislature. That's how I determine it. I'm not sure about what you asked me about August 20, 2020. Right, that was the letter. Right, there were letters that were sent over there. There were, I think, two letters. Well, there was one official letter, and I think that was information that went over there as well, saying these are the number of deaths, and that came from the Department, you know, from the Department probably prior to – put together prior to my August testimony.

Q. At this point were you comfortable when you sent the letter over, were you comfortable with the numbers?

[1011] *Id.* at 122-123.
[1012] Zucker TI, *supra* note 905, at 179-180.

A. The letter that I sent over in October, I was totally comfortable with. That was the number of deaths at that time.[1013]

Dr. Zucker believed that the numbers did not need to be audited further, and by not releasing the data the Cuomo Administration was simply "delaying."

Dr. Howard Zucker (December 18, 2023)

Q. Do you believe that [the number of deaths] needed to be audited further?

A. No. No. I felt that this letter should go.

Q. And again, this is your personal opinion. At this point any delay in releasing the numbers was just a delay?

A. Yeah, I felt it was a delay. I felt it should go out, and I will be the first to say that I raised it multiple times about getting them out, and had some days that I thought if they were so worried about something then they should put it out on X day or Y day. So like Thanksgiving.[1014]

Mr. Cuomo testified that he neither recalled Mr. Rhodes nor Dr. Zucker advising him to release the full data set.[1015] In response to Mr. Rhodes' audit, Mr. Cuomo noted that Mr. Rhodes "wasn't an auditor."[1016] Mr. Cuomo testified that Mr. Rhodes would not have advised releasing the numbers.[1017]

In response to the letters that Dr. Zucker drafted releasing the full data set, Mr. Cuomo denied ever reviewing them, saying that those letters would have been reviewed by the attorneys responding to the DOJ inquiry.[1018] Mr. Cuomo testified that the Executive Chamber had notified the New York state Legislature that they would release out-of-facility death totals in January 2021.

Mr. Andrew Cuomo (June 11, 2024)

Q. It's been widely reported that on a phone call with the legislature, Ms. DeRosa said the state froze in response to the DOJ's request. Is that the situation you're referencing?

[1013] *Id.* at 180-181.
[1014] Zucker TI, *supra* note 905, at 181.
[1015] Cuomo TI, *supra* note 907, at 275.
[1016] *Id.*
[1017] *Id.* at 276.
[1018] *Id.* at 279.

A. Froze meaning we had to make sure everything was careful. We had to be careful and make sure everything was right. That's what she was referring to. They both made requests at about the same time. The legislature made a request about August, the DOJ letter comes in about August. We called the legislative leaders and say, Can we do it in January because we have to be very careful because we have this purely political witch hunt going on at the Department of Justice run by two really bad guys. And that's what she's referring to.

…

Q. You mention that you asked the legislature if you could pause responding…[W]ho specifically spoke to the legislature from your office?

A. It would have been the governmental person, it could have been Beth or if it was the counsel or it could have been Melissa.

Q. You're saying that in August of 2020, you asked to wait until January 2021?

A. Somewhere around there, yeah.[1019]

Ms. DeRosa similarly testified that because of the ongoing DOJ investigation there was an agreement with the legislature to delay releasing the numbers until January 2021.

Ms. Melissa DeRosa (June 23, 2024)

Q. What happened to [Dr. Zucker's] letter? Did it make its way to the legislature?

A. No, the plan stayed the same. We were going to get back to [the legislature] in January with the hearing with the agreement that we had reached with the leaders.

Q. Why?

A. Well, I can give the reason I believe. I don't remember, like – I don't remember having any thought towards this in realtime. But after the Jeff Clark letter came in on October 28th, it was sort of like back to square zero, if that makes any sense. We were now in a situation where we were dealing with the Department of Justice, they had a fresh inquiry, and we needed to be responding to them. And while we did that, we were waiting on the legislature. We had every

[1019] *Id.* at 282.

intention of keeping our word to the legislature, which was to get back to them by their first hearing when they came back and resumed session in January. But that was not our priority. Our priority was getting back to DOJ.[1020]

FINDING:	Mr. Andrew Cuomo Acted in a Manner Consistent with an Attempt to Inappropriately Influence the Testimony of a Witness and Obstruct the Select Subcommittee's Investigation.

Dr. Malatras was the only Executive Chamber official to testify to the Mr. Cuomo's involvement in the July 6 Report prior to Ms. Kennedy testifying similarly on October 8, 2024.[1021] Senior Executive Chamber officials involved with the July 6 Report, including Ms. DeRosa, Ms. Lacewell, and Ms. Garvey, testified that they had no knowledge or recollection of Mr. Cuomo being involved in the July 6 Report.[1022]

Dr. Malatras testified about his most recent communications with former Governor Cuomo.

Dr. James Malatras (May 20, 2024)

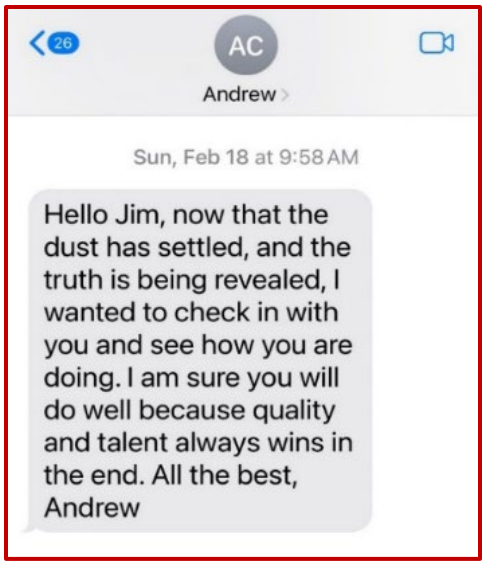
Q. Since January 2023, have you had any conversations with the former governor… about our investigation?

A. I have had no conversations with the governor since sometime in early 2021. He did text me several times to check in. The latest time he texted me was February 18th of this year, I believe, just to say I hope you're doing well, things like that. I did not respond…[1023]

It is the Select Subcommittee's understanding that, at the time of his transcribed interview, Dr. Malatras did not respond to any of the text messages he received from Mr. Cuomo and, consistent with his testimony, the Select Subcommittee stated Dr. Malatras had not "spoken" to former Governor Cuomo since 2021.

Subsequent to Dr. Malatras' transcribed interview, the Select Subcommittee requested the referenced text message from Mr. Cuomo to Dr. Malatras from February 18, 2024.[1024]

[1020] DeRosa TI, *supra* note 910, at 83.
[1021] Ms. Kennedy testified to the involvement of Mr. Cuomo after reviewing documents obtained by the Select Subcommittee.
[1022] Garvey TI, *supra* note 918, at 163; Lacewell TI, *supra* note 920, at 58; DeRosa TI, *supra* note 910, at 238.
[1023] Malatras TI, *supra* note 950, at 30.
[1024] Text from Andrew Cuomo, former Governor of New York, to Dr. Jim Malatras, former Advisor to the Governor (Feb. 18, 2024).


26
AC
Andrew
Sun, Feb 18 at 9:58 AM
Hello Jim, now that the dust has settled, and the truth is being revealed, I wanted to check in with you and see how you are doing. I am sure you will do well because quality and talent always wins in the end. All the best, Andrew

Considering the timing of this text message—within 48 hours of the Select Subcommittee publicly announcing its request for Dr. Malatras' testimony—and the fact that he had not spoken with former Governor Cuomo since 2021, the Select Subcommittee determined:

> …this text message raises concerns that Mr. Cuomo may have been trying to influence Dr. Malatras' testimony and obstruct the Select Subcommittee's investigation.

Mr. Cuomo testified the text message was "it's just a nice note" and that he was not aware of the Select Subcommittee's letter to Dr. Malatras.

Mr. Andrew Cuomo (June 11, 2024)

Q. [The text was sent] 48 hours after Dr. Malatras received an invitation to testify before us.

A. I hadn't spoken to Jim. I don't think I spoke to him since this period of time period. I think this was just saying – he went through a very tough time and was forced to resign from the state university system, and I think I'm saying to him – I think that's what this is in reference to… There was also ongoing conversations with Jim and litigation with him and I've known him a long time. He's a great fellow and he was getting beaten up, and I think I was just saying to him, you know, you're a good man.

Q. To the best of your recollection, when was the last time you contacted Dr. Malatras before this text?

A. I don't think I've spoken to Jim since I left as governor.

Q. I guess it's just a coincidence that Dr. Malatras got this text message within two days of getting an invitation to testify on nursing homes.

A. I didn't know that Jim – I haven't had – I haven't had conversations with Jim. Jim never told me he was coming here to testify.

Q. Were you aware that he received a letter, though?

A. No.

Q. So this text wasn't – you weren't trying to influence his testimony in any way by sending this text message?

A. No.

Q. Have you attempted to influence the testimony of any witness providing information concerning your administration's response to this Select Subcommittee?

A. No. By the way, this is just a nice note to a person.

…

A. I don't ask to speak with him. I don't suggest anything. It's just a nice note.[1025]

On September 9, 2024, Counsel for Mr. Cuomo e-mailed Select Subcommittee staff to express her objections regarding the Select Subcommittee's determination regarding this text message. [1026]

I explained that there was nothing nefarious about this text from which you could suggest Governor Cuomo may have been trying to influence Dr. Malatras's testimony or obstruct the Subcommittee's investigation…

I told you that if Dr. Malatras did not understand this innocuous text in that way, you could not suggest something nefarious by Governor Cuomo and you should note that Dr. Malatras did not testify he understood or thought there may have been a nefarious purpose…

The RSM [Republican Staff Memo] deliberately misleads the public by omitting…the fact that [Dr. Malatras] never told you that he understood the text message to be an effort to improperly influence him or obstruct this

[1025] Cuomo TI, *supra* note 907.
[1026] E-Mail from Ms. Rita Glavin, Counsel for Mr. Andrew Cuomo, to Select Subcommittee Staff (Sept. 9, 2024, 2:30 PM).

> investigation. Your suggestions that Governor Cuomo may have been attempting violate [sic] the law are entirely unsupported.

To address Counsel for Mr. Cuomo's concerns, Select Subcommittee staff replied and stated:

> Since Dr. Malatras was not asked explicitly how he [interpreted] the text, it is likely we send an interrogatory to Dr. Malatras to ask him what his interpretations or feelings were. Once we receive his response, we will make sure the memo is updated top [sic] include both his testimony and Mr. Cuomo's.[1027]

Counsel for Mr. Cuomo went further than simply expressing her objections and "reminded" Select Subcommittee staff of their ethical obligations.[1028] Counsel for Mr. Cuomo did this by referencing two staffers' applicable state bar rules—meaning she researched their state bar numbers—and cited the disbarment case against former New York City Mayor Rudolph Guiliani.[1029] A reasonable person may perceive this "reminder" as a threat to file disbarment complaints against those staffers. This is not the first time that Counsel for Mr. Cuomo has resorted to such intimidation tactics on Select Subcommittee staff.[1030]

On September 26, 2024, to address Counsel for Mr. Cuomo's objections, the Select Subcommittee sent interrogatories to Dr. Malatras.[1031] These interrogatories were targeted to address Counsel for Mr. Cuomo's concerns, including whether there were more communications between Mr. Cuomo and Dr. Malatras, and how Dr. Malatras interpreted the communications. On September 19, 2024, the Select Subcommittee received Dr. Malatras' supplemental testimony.[1032]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1027] E-Mail from Select Subcommittee Staff to Ms. Rita Glavin, Counsel for Andrew Cuomo (Sept. 10, 2024, 10:58 AM).
[1028] E-Mail from Ms. Rita Glavin, Counsel for Mr. Andrew Cuomo, *supra* note 1026; *See also,* Dan Diamond, *Andrew Cuomo, once a pandemic star, grilled by Congress over pandemic missteps*, THE WASH. POST. (Sept. 10, 2024) ("Rich Azzopardi, a Cuomo spokesman, said his colleagues were 'reminding' House lawyers that there were consequences for making "false and misleading" statements in the report that Republicans issued Monday. 'I do think lawyers have an ethical obligation to tell the truth, and I don't think there's a lot of that in this report,' Azzopardi said.").
[1029] *Id.*
[1030] E-Mail from Ms. Rita Glavin, Counsel for Mr. Andrew Cuomo, to Select Subcommittee Staff (Mar. 8, 2024, 5:07 PM).
[1031] Letter from Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, to James Malatras, Former Advisor, Governor of the States of N.Y., (Sept. 16, 2024).
[1032] Letter from James Malatras, Former Advisor, Governor of the States of N.Y., to Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability (Sept. 19, 2024) [hereinafter "Malatras Letter"].

May 17, 2023: The Select Subcommittee held a hearing entitled, "Like Fire Through Dry Grass: Nursing Home Mortality & COVID-19 Policies."[1033] At this hearing, Members of the Select Subcommittee questioned, on a bipartisan basis, Mr. Cuomo's March 25 Directive and the data regarding how the State of New York calculated nursing home deaths.[1034]

LIKE FIRE THROUGH DRY GRASS: NURSING HOME MORTALITY AND COVID–19 POLICIES

HEARING

BEFORE THE

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC

OF THE

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

MAY 17, 2023

Serial No. 118–33

Printed for the use of the Committee on Oversight and Accountability

Available on: govinfo.gov, oversight.house.gov or docs.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

52-343 PDF WASHINGTON : 2023

Chairman Brad Wenstrup (May 17, 2023)

…Today we heard concerning testimony regarding the manipulation of data from Governor Cuomo's own office. The Biden Department of Justice chose not to investigate the state orders nor the ensuing coverup. We will.

…

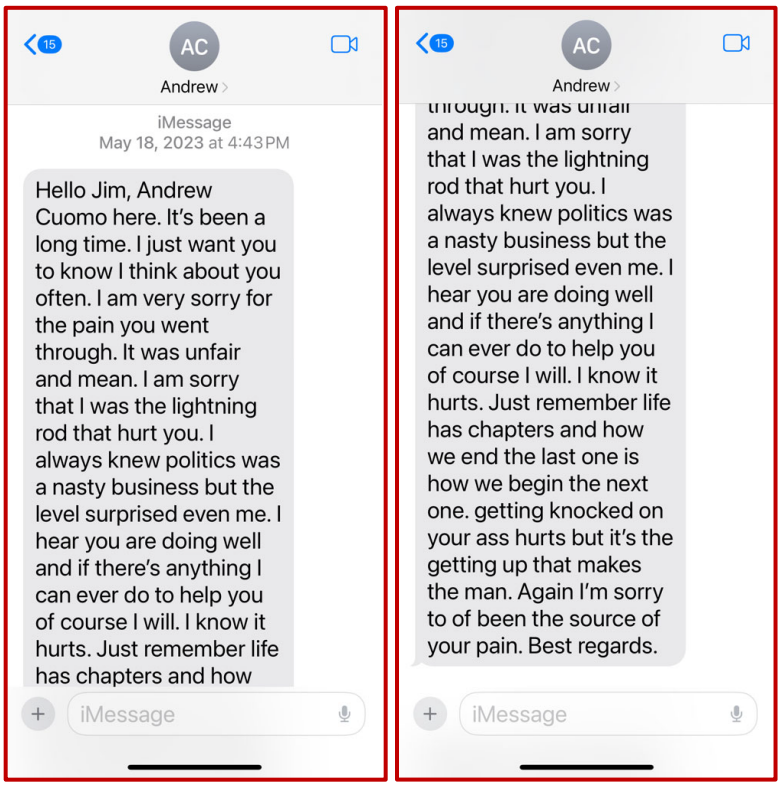
The Select Subcommittee on the Coronavirus Pandemic will continue to examine the deadly policy decisions surrounding nursing homes, and we will continue to investigate the failed leadership of state officials during the COVID–19 pandemic.

Chairman Wenstrup promised a thorough investigation into New York nursing home mortality and policies.[1035] The Chairman specifically noted that the Select Subcommittee would investigate the March 25 Directive, the issues surrounding the potential concealment of applicable nursing home data, and the July 6 Report.

Considering Dr. Malatras' position on Mr. Cuomo's Task Force and his involvement in the July 6 Report, including on the issues surrounding nursing home data, it would be logical for Mr. Cuomo to safely assume that Dr. Malatras would likely be a witness in the Select Subcommittee's investigation and have information potentially damaging to Mr. Cuomo.

May 18, 2023: Within 24 hours of the Select Subcommittee holding its first hearing on its investigation into New York nursing homes and for the first time since early 2021, Mr. Cuomo contacted Dr. Malatras. Mr. Cuomo sent the following text message to Dr. Malatras. Dr. Malatras did not respond.

[1033] Like Fire Through Dry Grass, *supra* note 934.
[1034] *Id.*
[1035] *Id.*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AC
Andrew
iMessage
May 18, 2023 at 4:43 PM
Hello Jim, Andrew Cuomo here. It's been a long time. I just want you to know I think about you often. I am very sorry for the pain you went through. It was unfair and mean. I am sorry that I was the lightning rod that hurt you. I always knew politics was a nasty business but the level surprised even me. I hear you are doing well and if there's anything I can ever do to help you of course I will. I know it hurts. Just remember life has chapters and how
iMessage
15
AC
Andrew
and mean. I am sorry that I was the lightning rod that hurt you. I always knew politics was a nasty business but the level surprised even me. I hear you are doing well and if there's anything I can ever do to help you of course I will. I know it hurts. Just remember life has chapters and how we end the last one is how we begin the next one. getting knocked on your ass hurts but it's the getting up that makes the man. Again I'm sorry to of been the source of your pain. Best regards.
iMessage

February 16, 2024: The Select Subcommittee requested Dr. Malatras' testimony at a voluntary transcribed interview.[1036] *The New York Post* publicly reported the Select Subcommittee's request to Dr. Malatras.[1037]

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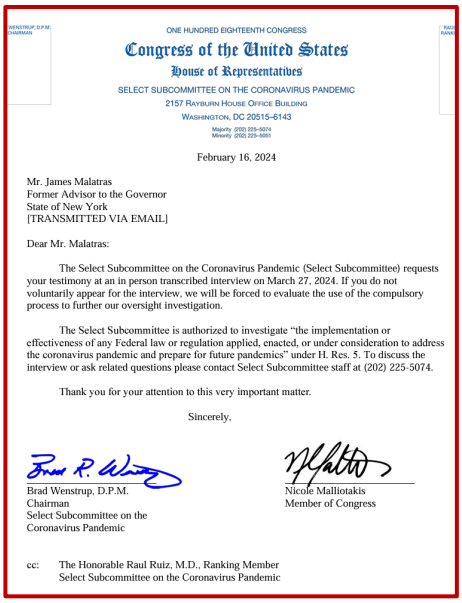
[1036] Letter from Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, to James Malatras, Former Advisor, Governor of the States of N.Y. (Feb. 16, 2024).
[1037] Victor Nava, *House COVID-19 panel requests testimony from 4 former Cuomo admin officials*, N.Y. POST (Feb. 16, 2024) (While the former Governor testified that he was not aware that the Select Subcommittee had requested Mr. Malatras' testimony, his spokesman, Rich Azzopardi was able to provide a statement on his behalf to this article in response to the Select Subcomittee's requests for transcribed interviews with Mr. Malatras' and others).



ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC

2157 Rayburn House Office Building

Washington, DC 20515-6143

Majority (202) 225-5074
Minority (202) 225-5051

February 16, 2024

Mr. James Malatras
Former Advisor to the Governor
State of New York
[TRANSMITTED VIA EMAIL]

Dear Mr. Malatras:

The Select Subcommittee on the Coronavirus Pandemic (Select Subcommittee) requests your testimony at an in person transcribed interview on March 27, 2024. If you do not voluntarily appear for the interview, we will be forced to evaluate the use of the compulsory process to further our oversight investigation.

The Select Subcommittee is authorized to investigate "the implementation or effectiveness of any Federal law or regulation applied, enacted, or under consideration to address the coronavirus pandemic and prepare for future pandemics" under H. Res. 5. To discuss the interview or ask related questions please contact Select Subcommittee staff at (202) 225-5074.

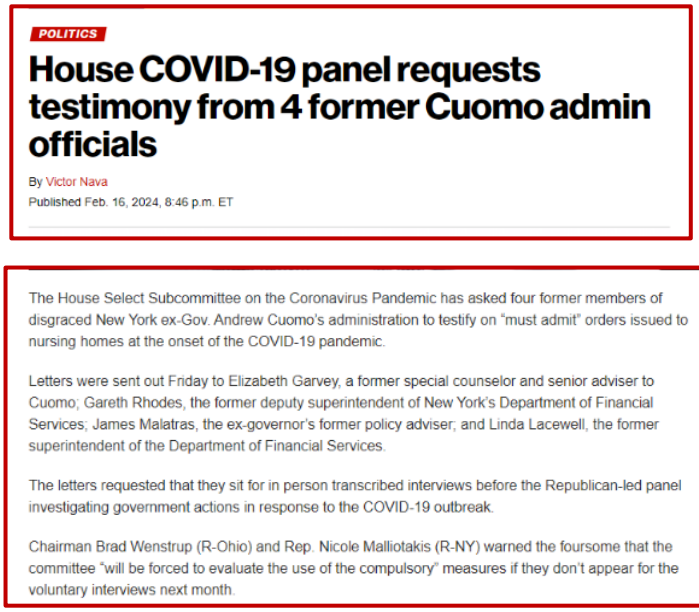
Thank you for your attention to this very important matter.

Sincerely,

Brad Wenstrup, D.P.M.
Chairman
Select Subcommittee on the
Coronavirus Pandemic

Nicole Malliotakis
Member of Congress

cc: The Honorable Raul Ruiz, M.D., Ranking Member
Select Subcommittee on the Coronavirus Pandemic



POLITICS

House COVID-19 panel requests testimony from 4 former Cuomo admin officials

By Victor Nava
Published Feb. 16, 2024, 8:46 p.m. ET

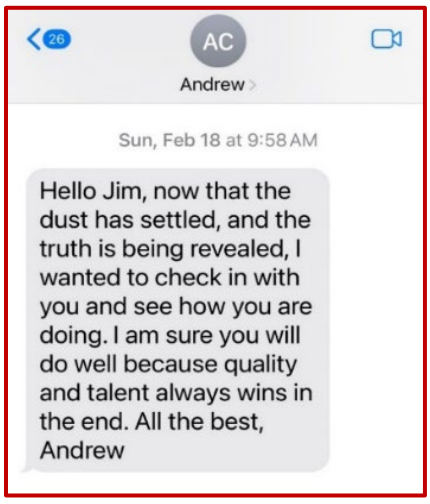
The House Select Subcommittee on the Coronavirus Pandemic has asked four former members of disgraced New York ex-Gov. Andrew Cuomo's administration to testify on "must admit" orders issued to nursing homes at the onset of the COVID-19 pandemic.

Letters were sent out Friday to Elizabeth Garvey, a former special counselor and senior adviser to Cuomo; Gareth Rhodes, the former deputy superintendent of New York's Department of Financial Services; James Malatras, the ex-governor's former policy adviser; and Linda Lacewell, the former superintendent of the Department of Financial Services.

The letters requested that they sit for in person transcribed interviews before the Republican-led panel investigating government actions in response to the COVID-19 outbreak.

Chairman Brad Wenstrup (R-Ohio) and Rep. Nicole Malliotakis (R-NY) warned the foursome that the committee "will be forced to evaluate the use of the compulsory" measures if they don't appear for the voluntary interviews next month.

February 18, 2024: Within 48 hours of the Select Subcommittee's letter, and for the second time since 2021, Mr. Cuomo contacted Dr. Malatras again.


26
AC
Andrew
Sun, Feb 18 at 9:58 AM
Hello Jim, now that the dust has settled, and the truth is being revealed, I wanted to check in with you and see how you are doing. I am sure you will do well because quality and talent always wins in the end. All the best, Andrew

In response to interrogatories from the Select Subcommittee, Dr. Malatras stated that he believed this text to be in response to the Select Subcommittee's letter.[1038] Further, Dr. Malatras stated that this text message was a "flare—or signal—alerting [him] that [former Governor Cuomo] was aware" of Dr. Malatras' upcoming testimony.

Dr. James Malatras (September 19, 2024)

[1038] Malatras Letter, *supra* note 1032.

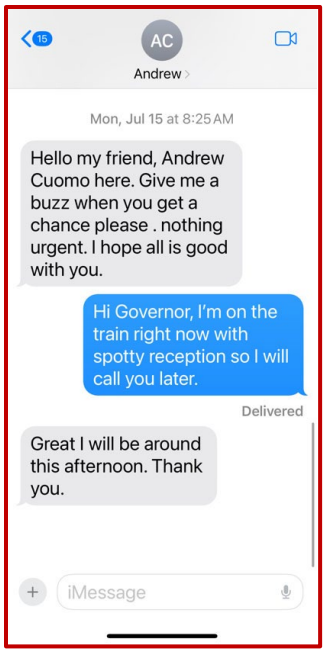
Q.	Dr. Malatras, to you, was the February 18, 2024 text message from Mr. Cuomo to you in response to the Select Subcommittee's invitation for your testimony?
A.	Yes.
Q.	Dr. Malatras, how did you interpret the content of the February 18, 2024 text message from Mr. Cuomo to you?
A.	I took it as a type of flare—or signal— alerting me that he was aware that the House Select Subcommittee had requested that I testify on issues related to the administration's handling of the Covid-19 response.[1039]

July 15, 2024: After negotiating for a week, the Select Subcommittee, Mr. Cuomo, and Counsel for Mr. Cuomo agreed to a public hearing on September 10, 2024 with Mr. Cuomo as the sole witness. To secure Mr. Cuomo's voluntary cooperation, the Select Subcommittee agreed to not publicly announce the date until required pursuant to the rules of the Committee on Oversight and Accountability—seven days prior to the hearing date.[1040]

July 15, 2024: The same day the hearing was confirmed and for the first time in more than three years, Mr. Cuomo called Dr. Malatras.[1041] Dr. Malatras did not answer.[1042] Mr. Cuomo followed up by text.[1043]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1039] *Id.*
[1040] E-Mail from Ms. Rita Glavin, Counsel for Andrew Cuomo, to Select Subcommittee Staff (July 15, 2024, 6:38 PM).
[1041] Malatras Letter, *supra* note 1032.
[1042] *Id.*
[1043] *Id.*


15
AC
Andrew
Mon, Jul 15 at 8:25 AM
Hello my friend, Andrew Cuomo here. Give me a buzz when you get a chance please . nothing urgent. I hope all is good with you.
Hi Governor, I'm on the train right now with spotty reception so I will call you later.
Delivered
Great I will be around this afternoon. Thank you.
iMessage

Dr. Malatras stated that he and Mr. Cuomo spoke later that day around 5:00 p.m. for about half an hour and Mr. Cuomo discussed his upcoming testimony before the Select Subcommittee and the nursing home investigation specifically.[1044] Dr. Malatras stated that he did not engage in that conversation because he was "uncomfortable."

As far as the Select Subcommittee is aware, at the time of this call, Mr. Cuomo and his Counsel were the only ones, outside of the Select Subcommittee, with knowledge of the upcoming hearing.

Dr. James Malatras (September 17, 2024)

Q. Dr. Malatras, have you been contacted by Mr. Cuomo since your May 20, 2024 interview before the Select Subcommittee?

A. Yes.

Q. …[D]id Mr. Cuomo discuss issues related to the Select Subcommittee?

A. Yes.

Q. …[W]hat topics?

A. Governor Cuomo started the call by mentioning he would be testifying publicly in front of the House Select Subcommittee. As

[1044] *Id.*

part of the conversation he spoke about nursing homes, specifically describing how the story in New York was much better than I even knew it to be and mentioned several facts and datapoints to demonstrate his point. I don't recall the exact details of the facts or datapoints but recall generally that he mentioned that New York's nursing home numbers in comparison to other states were even better than first thought.

Q. …[H]ow did you interpret the phone call?

A. For the portion of the call regarding the Select Subcommittee, I interpreted the call as an effort to make me aware of the positive information about which he intended to testify. I only listened and did not respond to his discussion on nursing homes, because I was uncomfortable having to potentially contradict or disagree with Governor Cuomo on the call, or somehow prejudicing the upcoming Select Subcommittee hearing by discussing it at all.[1045]

FINDING: Andrew Cuomo Likely Gave False Statements to the Select Subcommittee in Violation of 18 U.S.C. 1001.

The Select Subcommittee believes that Mr. Cuomo made false statements about his involvement in and knowledge of the drafting of the July 6 Report. On October 30, 2024, The Select Subcommittee referred Mr. Cuomo to DOJ pursuant to 18 U.S.C. § 1001.[1046]

That same day, Mr. Cuomo, via Counsel, transmitted a referral of the Select Subcommittee to DOJ for no articulated violation of law, but instead, a vague reference to "misuse of government resources and the invasion of state prerogatives."[1047] As a preliminary matter, this referral has no basis in fact. Additionally, Mr. Cuomo's Counsel intentionally truncated the Select Subcommittee's jurisdiction in an apparent attempt to give the appearance of a lack of jurisdiction.[1048] Further, it appears that Mr. Cuomo's position is that a citizen of the U.S. no longer retains their First Amendment Right and is disallowed from petitioning their government, if they are simultaneously availing themselves of the justice system. This position is in clear divergence with the rights afforded to Americans and runs afoul of the founding principles of the U.S.

[1045] *Id.*
[1046] Letter from Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, to Hon. Merrick Garland, Attorney General, Dep't of Justice (Oct. 30, 2024); Referral of Andrew M. Cuomo, Select Subcomm. on the Coronavirus Pandemic (Oct. 30, 2024).
[1047] Letter from Sarah Sulkowski, Counsel for Andrew Cuomo, to Hon. Merrick Garland, Attorney Gen., U.S. Dep't of Justice (Oct. 30, 2024).
[1048] *Id.*

Subsequent to the referral, Mr. Cuomo, again via Counsel, transmitted a letter to DOJ in his defense of the Select Subcommittee's referral.[1049] In this letter, Counsel for Mr. Cuomo stated, "[t]he grotesque political nature of the Wenstrup Referral is also revealed by its inclusion of a footnote that cites to the discredited, biased, and hopelessly flawed investigation of sexual harassment allegations against Governor Cuomo by the New York Attorney General ("OAG")."[1050]

Mr. Cuomo's aversion to the New York Attorney General in this case is contradictory to Mr. Cuomo's praise for the Attorney General at his public hearing before the Select Subcommittee.

> **The Attorney General of New York, who governs the New York law and interprets the New York law**, found exactly contrary to what you are saying, and said it repeatedly, and you know she said it repeatedly.
>
> ***
>
> The March 25 guidance was consistent with the CMS guidance. The March 25 guidance was consistent with the CMS guidance if nursing homes have the ability to adhere to infection prevention and control recommendations. It was also consistent with CDC-published transmission-based precautions. **That's the attorney general's position and opinion, and that's the law of the state of New York**.[1051]

[1049] Letter from Ms. Rita Glavin, Counsel for Andrew Cuomo, to Hon. Merrick Garland, Att'y Gen., U.S. Dep't of Justice (Oct. 31, 2024).
[1050] *Id.*
[1051] A Hearing with Former New York Governor Andrew Cuomo: Hearing Before Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 2 (Sept. 10, 2024) [hereinafter "Cuomo Hearing"].

VIII. While Testing for COVID-19 Was Flawed, Utilizing Public-Private Partnerships Resulted in Readily Available and Accurate Tests

Historically, the CDC has taken the lead on developing tests for new diseases and distributing the tests through the public health laboratory network.[1052] Once the genetic sequence of COVID-19 was identified, the CDC assumed initial responsibility for developing COVID-19 test kits.[1053] The agency produced a diagnostic test, which was distributed to public health laboratories in early February 2020.[1054] However, issues with the test's accuracy led to delays in widespread testing. The FDA began issuing EUAs[1055] in February 2020 to allow labs and manufacturers to develop, validate, and distribute COVID-19 tests.[1056] EUAs allowed for quicker deployment of tests without going through the typical, lengthier approval process.

As the CDC's tests were limited and, therefore, hindered testing capacity, the federal government encouraged private companies and laboratories to develop their own tests. In March 2020, commercial laboratories, such as Quest Diagnostics and LabCorp, were approved to develop and distribute tests, which significantly expanded testing capacity.[1057] Additionally, the federal government partnered with private industry to increase testing capabilities, including the launch of drive-through testing sites in collaboration with companies like Walmart, Walgreens, CVS, and others.[1058] The COVID-19 Testing Supply Chain Stabilization Task Force was also created to address shortages of testing materials.[1059]

In addition to developing and distributing tests, the federal government also issued testing guidance. Early on in March 2020, the CDC's testing guidelines prioritized people who were symptomatic, had traveled to affected areas, or were exposed to confirmed cases.[1060] Healthcare workers and those in critical roles were also prioritized due to limited testing capacity.[1061] As testing availability expanded by June of 2020, the CDC updated its guidelines to include asymptomatic individuals, especially those in high-risk settings like long-term care facilities or prisons.[1062] The guidance gradually shifted to encourage broader testing.

[1052] U.S. DEP'T OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, A-04-20-02027, *CDC's Internal Control Weaknesses led to its initial COVID-19 Test Kit Failure, but CDC Ultimately Created a Working Test Kit*, at 4-5 (Oct. 2023) [hereinafter "HHS IG report"].
[1053] *Id.* at 6.
[1054] *Id.*
[1055] See below, "The Review of Pfizer's Biologics License Application," pg. 311.
[1056] HHS IG report, *supra* note 1502, at 6, figure 2.
[1057] Noah Weiland & Katie Thomas, *Trump Administration Moves to Speed Coronavirus Testing*, THE N.Y. TIMES (Mar. 13, 2020).
[1058] Amy Goldstein, *et al., Trump says he will partner with private sector to expand coronavirus testing but details are sketchy*, THE WASH. POST (Mar. 13, 2020).
[1059] *FEMA COVID-19 Supply Chain Task Force: Supply Chain Stabilization*, FEMA.
[1060] Roni Caryn Rabib & Katie Thomas, *Coronavirus Testing Offered With Just a Doctor's Approval, C.D.C. Says,* THE N.Y. TIMES (Mar. 4, 2020).
[1061] Carolyn Y. Johnson, *et al., In hard-hit areas, testing restricted to health care workers, hospital patients*, THE WASH. POST (Mar. 21, 2020).
[1062] *COVID-19 timeline*, U.S. CTRS. FOR DISEASE AND CONTROL (June 13, 2020) (CDC releases consolidated guidelines for COVID-19 testing— including for nursing homes, long-term care facilities, and high-density critical infrastructure workplaces, like food production facilities.)

The federal government also provided funding to facilitate testing. There was significant financial support for testing through the CARES Act, which allocated billions of dollars for testing and disease surveillance.[1063] This funding helped expand testing sites, purchase testing supplies, and support state and local public health efforts. The Health Care Enhancement Act allocated an additional $25 billion for testing, including funds for states, territories, and tribes to develop testing plans and increase capacity.[1064]

FINDING:	Career Scientists at the U.S. Centers for Disease Control and Prevention Undermined Trust in Public Health by Overpromising and Underdelivering Early Testing Kits, Including Knowingly Putting Tests with a High Failure Rate on the Market Without Appropriate Disclosures.

In the early stages of the pandemic, states sent samples to the CDC, which then tested those samples in its labs.[1065] Although the CDC has limited capacity to conduct these tests, Dr. Redfield testified that samples from states were not refused by the CDC, albeit it may have taken several days to test those samples.[1066] States wanted their own test kits so that they could test their own samples, and the CDC sought to facilitate that request.

Dr. Redfield was not involved in the CDC's development of these test kits.[1067] In fact, Dr. Redfield testified that the CDC is "not a manufacturing company [and] had [he] been involved in those decisions at the time, [he] would have recommended a contract manufacturing company manufacture [the test kits]."[1068]

While the CDC's career scientists' desire to quickly develop these test kits was laudable, the execution was disastrous. These career scientists assured the public that reliable, widespread testing would soon be accessible, helping to contain outbreaks and protect public health.[1069] These officials opted to develop their own test kits rather than use tests already approved and distributed internationally[1070] or seek assistance from industry. This slowed the process significantly and prevented wider access to testing.

The CDC's first batch of COVID-19 test kits, distributed in February 2020, were found to be faulty due to contamination issues.[1071] These tests that were rushed to market without

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[1063] *See*, CARES Act, *supra* note 396.
[1064] *Id.*
[1065] Transcribed Interview of Robert Redfield, M.D., Former Dir., U.S. Ctrs. for Disease and Control, at 43 (Mar. 17, 2022).
[1066] *Id*.
[1067] *Id.* at 75 ("There were people at the states, obviously a number of them said it would be easier for them if they could do the tests themselves. And people at CDC had decided that they would try to facilitate that. And this is not something I was engaged in the decision making at the time. But the lab group and the incident command group decided that the lab team would develop reagents that then they would distribute to the public health labs.").
[1068] *Id.*
[1069] Arman Azad, *WHO and CDC never discussed providing international test kits to the US, global health agency says*, CNN (Mar. 18, 2020).
[1070] *Id*.
[1071] Dina Temple-Raston, *CDC Report: Officials Knew Coronavirus Test Was Flawed But Released It Anyway*, NPR (Nov. 6, 2020).

sufficient validation had high failure rates. These included both false positives and false negatives, which undermined the reliability of testing as a public health tool.[1072]

However, within weeks of distribution, it was discovered that the tests were producing inconclusive results due to a flaw in one of the components used in the chemical analysis (referred to as a "reagent") of the collected sample.[1073] This flaw led to a significant delay in the ability of public health labs to conduct tests, leaving the U.S. blind to the early spread of the virus. These issues led to delays in testing at a critical time when the virus was beginning to spread widely in the U.S. Despite the promises of widespread testing, many areas of the country faced severe shortages of tests, leading to long wait times for results and a lack of timely data to inform public health decisions. There were instances where CDC scientists did not fully disclose the limitations and failure rates of certain tests.[1074] For example, some tests that were approved by the FDA under EUAs were later found to be less accurate than initially reported.[1075]

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[1072] *Summary of the Findings of the Immediate Office of the General Counsel's Investigation Regarding CDC's Production of COVID-19 Test Kits*, DEP'T OF HEALTH AND HUMAN SERVICES (June 19, 2020) *available at* https://www.documentcloud.org/documents/6953861-6-19-20-Summary-of-the-Findings-of-the-Immediate.html.
[1073] *Id*.
[1074] Dan Vergano, *The Government Asked Us Not To Release Records From The CDC's First Failed COVID Test. Here They Are*, BUZZFEED NEWS (Dec. 8, 2021).
[1075] *Id.*

Figure 2: Initial COVID-19 Test Kit Production Timeline

(Specific dates are in parentheses.)

DECEMBER 2019

(31) The World Health Organization (WHO) notes several cases of viral pneumonia in Wuhan, China.

JANUARY 2020

(9) CDC activates a Center-Led Response.

(10) Researchers in China post the genome sequence for COVID-19. CDC begins creation of the COVID-19 test kit.

(18) CDC CLIA lab is approved to use COVID-19 test on human samples.

(20) First U.S. case of the novel coronavirus is confirmed by CDC.

(21) CDC activates the EOC for an Agency-Wide Response.

(24) CDC publicly posts the procedure and sequences for its COVID-19 assay, allowing others the ability to develop similar test kits.

(30) WHO declares a public health emergency of international concern.

(31) HHS declares a national public health emergency for the United States.

FEBRUARY 2020

(1) Test kit is assembled.

(2) CDC ships test kits to intermediary for distribution to PHLs.

(4) FDA issues EUA for CDC's COVID-19 test kit.

(6) Initial COVID-19 test kits are distributed to PHLs.

(8) PHLs begin to report problems with COVID-19 test kits.

(10) CDC begins to troubleshoot COVID-19 test kit problems.

(28) Second COVID-19 test kits are distributed to PHLs.

MARCH 2020

(15) FDA reissues EUA.

The combination of overpromising, delays, and the release of unreliable tests created confusion and frustration among the public. This confusion was compounded by mixed messages from federal officials, which further eroded trust. The initial missteps in testing not only hampered efforts to control the pandemic but also had long-lasting effects on public trust in government and public health institutions. The perception that CDC scientists had misled the public about the availability and effectiveness of testing contributed to skepticism about other public health measures, including vaccination.

Although CDC scientists eventually acknowledged the problem with the test kits, the delay in addressing the issue and the lack of initial transparency contributed to a growing

mistrust in the public health officials' handling of the pandemic. The failure of the CDC's early test kits highlighted the need for more rigorous testing and validation procedures before rolling out diagnostic tools in a public health emergency.

CDC scientists overpromising widespread and reliable testing, followed by the underdelivering of faulty and unreliable tests, created a significant gap between public expectations and reality. This gap, exacerbated by a lack of transparency about the limitations of early tests, contributed to a broader erosion of confidence in public health measures. Moving forward, it is essential that lessons from these early failures are used to improve the development, validation, and communication of public health interventions.

FINDING: Public-Private Partnerships Were More Effective in Increasing Testing Production, Distribution, and Capacity than Career Government Bureaucrats.

In the early stages of the pandemic, the CDC was tasked with developing and distributing diagnostic tests for COVID-19. However, as previously discussed the initial rollout was slow, and the tests produced by the CDC were plagued by inaccuracies and supply shortages. These early setbacks hindered the U.S.'s ability to rapidly scale up testing capacity and track the virus's spread. Furthermore, the CDC's focus on centralized control over test production and distribution created bottlenecks that delayed broader testing efforts.

By mid-March 2020, it became clear that public health authorities could not handle the growing demand for testing alone. The involvement of private industry, particularly diagnostic companies, biotechnology firms, and commercial laboratories, became essential to improve testing at scale. The shift to include the private sector catalyzed a rapid expansion in testing availability and quality.

Private industry played a pivotal role in increasing the production capacity for COVID-19 testing kits. Commercial diagnostic laboratories such as LabCorp, Quest Diagnostics, Abbott Laboratories, and Roche Diagnostics leveraged their established infrastructure and experience to ramp up production of both molecular [hereinafter "PCR"] and antigen-based testing kits.[1076] By mid-2020, these companies had significantly increased the daily output of tests, contributing to an exponential rise in the U.S.'s overall testing capacity.

For example, Abbott Laboratories [hereinafter "Abbot"]developed the BinaxNOW rapid antigen test, which became widely used due to its affordability, ease of use, and fast turnaround time.[1077] With FDA approval pursuant to an EUA, Abbott was able to produce millions of tests, vastly increasing access to COVID-19 diagnostics.[1078] Similarly, Roche Diagnostics produced

[1076] REPORT TO CONGRESS, COVID-19 STRATEGIC TESTING PLAN, at 11 U.S. DEP'T OF HEALTH AND HUMAN SERVICES (May 24, 2020).
[1077] Jessica Prince-Guerra, *et al., Evaluation of Abbott BinaxNOW Rapid Antigen Test for SARS-CoV-2 Infection at Two Community-Based Testing Sites — Pima County, Arizona, November 3–17, 2020*, MMWR (Jan. 22, 2021).
[1078] BINAXNOW COVID-19 Antigen Self Tests, Abbott, *available at* https://www.globalpointofcare.abbott/us/en/product-details/binaxnow-covid-19-antigen-self-test-us.html?utp=UTID&utid=SEM_G_BR_BinaxNOW_Tests&utm_term=abbott%20binaxnow%20home%20test&utm_source=google&utm_medium=cpc&gclid=Cj0KCQiAgJa6BhCOARIsAMiL7V90XdpTKJfKIxSfigZEpW9T_s8wGfO8emzrBSLWVwWWCRKDivXcP9UaAsCREALw_wcB&gclsrc=aw.ds#find-test.

PCR test kits that were widely regarded as the gold standard for accuracy and sensitivity.[1079] These efforts addressed the early shortages that had hampered public health official's initial testing strategy and helped ensure that supply could meet rising demand.

Private firms also utilized advanced manufacturing techniques to streamline production. This included innovations in automation, robotics, and supply chain optimization, which allowed testing kit production to scale up without sacrificing quality. The capacity to produce millions of tests weekly became a reality by mid-2020, largely due to private sector engagement.

Private industry's involvement not only increased testing capacity but also improved the quality and accuracy of COVID-19 tests. The CDC's initial test kits faced issues related to faulty reagents, which led to inconclusive results and hindered public health efforts. In contrast, many of the diagnostic tests developed by private companies demonstrated higher sensitivity and specificity, making them more reliable for detecting SARS-CoV-2, the virus that causes COVID-19.[1080]

Commercial laboratories invested heavily in research and development to improve test performance. Companies like Thermo Fisher Scientific and Hologic developed PCR tests that provided accurate results within 24 hours, while also reducing the likelihood of false negatives.[1081] Additionally, private companies played a critical role in developing rapid antigen tests, such as the Quidel Sofia test, which allowed for mass testing in settings like schools, workplaces, and nursing homes.[1082] These tests, although less sensitive than PCR tests, were crucial for identifying infectious individuals quickly and preventing outbreaks.[1083] Moreover, private industry ensured that testing quality remained consistent as production scaled up. Many companies adhered to stringent quality control measures, regularly validating their tests against CDC and FDA standards. This commitment to high-quality testing helped restore public confidence in the diagnostic tools available during the pandemic.

The ability of private industry to create efficient distribution networks was another key factor in the success of COVID-19 testing efforts. Early in the pandemic, testing was largely confined to hospitals and specialized laboratories, which were overwhelmed by demand. However, private companies, with their established logistics networks, were able to rapidly expand the distribution of test kits across the country. Retailers such as Walmart, Walgreens, and CVS partnered with diagnostic companies to open drive-through testing sites, providing easily accessible testing in parking lots and clinics nationwide. This decentralized approach allowed for

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[1079] Olena Filchakova, *et al., Review of COVID-19 testing and diagnostic methods,* SCIENCE DIRECT (July 1, 2022).
[1080] *Id.*
[1081] ThermoFisher Scientific *available* at https://www.thermofisher.com/us/en/home/life-science/pcr/digital-pcr.html?ef_id=EAIaIQobChMI-qzawqe7iAMVtkxHAR3s7R5CEAAYASAAEgIUvvD_BwE:G:s&s_kwcid=AL!3652!3!606132910994!p!!g!!thermofisher%20dpcr!17574808538!139287683938&cid=gsd_pcr_sbu_r02_co_cp1491_pjt9601_gsd00000_0se_gaw_rs_lgn_&gad_source=1&gclid=EAIaIQobChMI-qzawqe7iAMVtkxHAR3s7R5CEAAYASAAEgIUvvD_BwE.
[1082] Avalon, *Coronavirus Testing in the Outpatient Setting*, CARE SOURCE (effective date Nov. 1, 2022) *available at* https://avalonhcs.com/wp-content/uploads/CareSource/KYDSNP/G2174%20v3%20Coronavirus%20Testing%20in%20the%20Outpatient%20Setting%20efd;%2011-01-2022.pdf.
[1083] Greg Slabodkin, *COVID-19 antigen testing on par with PCR when used often: NIH-funded study,* MEDTECHDIVE (July 1, 2021).

more people to be tested in both urban and rural areas, reducing geographic disparities in testing availability. Furthermore, the private sector facilitated the distribution of test kits directly to state and local health departments, ensuring a more equitable allocation of resources.

Private industry also pioneered the development of at-home test kits, such as those created by Ellume and Everlywell.[1084] These tests enabled individuals to collect samples at home and receive rapid results within minutes. The introduction of at-home testing revolutionized accessibility, particularly for people who could not easily visit testing centers due to mobility issues or concerns about exposure to the virus in public settings.

Perhaps the most significant contribution of private industry to the COVID-19 response was the dramatic increase in testing capacity. As private laboratories and manufacturers entered the testing market, daily testing capacity rose from just a few thousand tests per day in early 2020 to more than one million tests per day by mid-2021.[1085] This increase was critical for controlling the spread of the virus, especially during periods of high transmission and the emergence of new variants.

The private sector's investment in high-throughput laboratory technology allowed for the processing of large volumes of tests in a short time. Laboratories like Quest Diagnostics and LabCorp implemented automation in their testing processes, reducing turnaround times and minimizing the backlog of unprocessed samples.[1086] Additionally, the introduction of rapid antigen tests provided a complementary approach to molecular testing, enabling quicker results for those in need of immediate diagnosis.

The success of private sector contributions underscores the importance of public-private partnerships in responding to large-scale health crises. As the world prepares for future pandemics, leveraging the expertise, resources, and agility of private industry will be essential for developing effective testing strategies and ensuring swift responses to emerging threats.

[1084] William Wan, *FDA authorizes first rapid, over-the-counter home coronavirus test*, THE WASH. POST (Dec. 15, 2020).
[1085] Laura Strickler & Adiel Kaplan, *Private labs do 85 percent of U.S. COVID-19 tests but still struggle with backlogs, shortages*, NBC NEWS (Apr. 8, 2020).
[1086] Will Feuer, *Quest says FDA cleared new 'lab method' that will cut coronavirus testing delays*, CNBC (July 29, 2020).

IX. Rapidly Implemented Travel Restrictions Can Save Lives

The COVID-19 pandemic led to an unprecedented series of global public health measures, with international travel-related control measures playing an early role in the U.S.' response. The effectiveness of these measures has been a subject of debate since the time they were imposed. The phrase "travel-related control measures " could include the following actions: "(1) border closure, (2) travel bans, (3) travel restrictions [e.g., a ban of persons who had been in certain countries with enumerated exceptions], (4) entry/exit screening, (5) travel-related quarantine and (6) . . . [a combination of different] travel-related control measures."[1087] For purposes of this report and as described below, the Trump Administration's actions early in the pandemic are best categorized as travel restrictions.

On January 31, 2020, as China reluctantly acknowledged that COVID-19 cases and deaths were rising in their country, the Trump Administration promulgated travel restrictions focused on China.[1088] Specifically, the U.S. suspended entry of all aliens, with a list of 11 enumerated exceptions, who were physically present in China 14 days prior to their entry or attempted entry into the U.S.[1089]

On March 12, 2020, the Trump Administration announced travel restrictions for an initial period of 30 days covering 26 European countries within the Schengen Area, which excludes the United Kingdom and Ireland.[1090] Two days later, the European travel restrictions were extended to travelers from the United Kingdom and Ireland and contained similar criteria (e.g., persons who were a covered country with 14 days from attempted entry in the U.S.) and exceptions to those in the order pertaining to China (e.g., lawful permanent residents, and their immediate family members could enter).[1091]

At the time of the European travel restrictions, COVID-19 had reached American shores. On March 12, 2020, there were more than 1,000 known cases in the U.S., but more than 125,000 known cases globally.[1092]

FINDING:	International Travel Restrictions Delayed the Spread of COVID-19 Early in the Pandemic.

The effectiveness of international travel restrictions in curbing the spread of COVID-19 remains a subject of contention among public health experts. While these bans were seen as crucial in the early stages of the pandemic, their long-term efficacy has been questioned.

[1087] Ani Movsisyan, *et al., Travel-related control measures to contain the COVID-19 pandemic: an evidence map*, BMJ OPEN (Apr. 2021).
[1088] Proclamation, White House, Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Persons who Pose a Risk of Transmitting 2019 Novel Coronavirus (Jan. 31, 2020).
[1089] *Id.* (The order excluded the Special Administrative Regions of Hong Kong and Macau.).
[1090] Saim Saeed, *Trump's Europe travel ban explained*, POLITICO (Mar. 12, 2020) (noting "[t]he 26 European countries in the Schengen zone — Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and Switzerland.).
[1091] Proclamation, White House, *supra* note 1088.
[1092] Contagion Live News Network: Coronavirus Updates for March 12, 2020, Contagion Live (Mar. 12, 2020).

By the end of January 2020, there were only seven known cases of COVID-19 in the U.S.[1093] At that point in time, the travel restrictions pertaining to China, the origin of the virus, were reasonably grounded in the belief that limiting international movement could prevent the introduction and spread of the virus in the U.S., particularly in the early stages of the pandemic before community transmission became widespread. Even as Europe became a hotspot for the virus by March of 2020, the known cases within the U.S. were at a manageable level—just more than 1,000.

With four years of hindsight, it is clear the international travel restrictions early in the pandemic delayed spread of the virus but did not prevent COVID-19 from entering the U.S. By the time the European travel ban was enacted in March 2020, it is now known that the virus had already spread significantly within the U.S. due to earlier untracked travel from Europe.[1094] However, the restrictions likely helped reduce the number of new cases entering the U.S. from Europe, where the virus was spreading rapidly at the time.

One study estimated that the U.S. travel bans helped to prevent approximately 77,000 cases of COVID-19 in the first month of their implementation.[1095] This study concluded that, while the travel restrictions did not entirely stop the virus from entering the U.S., they were effective in slowing the rate of transmission, giving the U.S. healthcare system more time to prepare and respond to the pandemic.[1096] A different study estimated that without the implementation of travel restrictions of persons coming from China, U.S. cases would have been 83 percent higher at the end of February 2020.[1097]

Contrary to baseless claims that the travel restrictions were pointless or worse the result of untoward motivations, on July 31, 2020, Dr. Fauci testified he supported the travel restrictions when questioned by then-Minority Whip Steve Scalise.

Dr. Anthony Fauci (July 31, 2020)

Q. Dr. Fauci, let me ask you about some of the decisions that you worked with President Trump on and the whole team did. I know when you go back to the beginning of this, the China ban was very heavily discussed. Were you involved in working with President Trump on deciding to ban flights from China?

[1093] *CDC Museum COVID-19 Timeline*, U.S. CTRS. FOR DISEASE CONTROL AND PREVENTION, *available at* https://www.cdc.gov/museum/timeline/covid19.html ("January 30, 2020: CDC confirms that the SARS-CoV-2 virus has now spread between two people in Illinois with no history of recent travel. This is the first recorded instance of person-to-person spread of the 2019 Novel Coronavirus in the U.S and brings the total number of cases up to seven.").
[1094] Bingyi Yang, *et al, Effectiveness of International Travel Controls for Delaying Local Outbreaks of COVID-19,* EMERGING INFECTIOUS DISEASES (Jan. 28, 2022).
[1095] Nicole A. Errett *et al*., *An integrative review of the limited evidence on international travel bans as an emerging infectious disease disaster control measure,* JOURNAL OF EMERGENCY MANAGEMENT (Jan. 1, 2020).
[1096] *Id.*
[1097] Nahae Kang & Beomsoo Kim, *The Effects of Border Shutdowns on the Spread of COVID*-19, JOURNAL OF PREVENTATIVE MEDICINE AND PUBLIC HEALTH (Aug. 30, 2020).

A. Yes, sir, I was.

Q. Do you agree with that decision?

A. I do.

Q. Do you think that decision saved lives, Dr. Fauci?

A. Yes, I do.

Q. Do you agree with the decision, when ultimately we saw spread in Europe and then the President recommended that we extend that to Europe, did you participate in that discussion?

A. I was actively involved in that discussion, sir.

Q. Do you agree with that decision?

A. Yes, I do.

Q. Do you think that decision saved lives?

A. Yes, I do.

Q. Eventually, then, we saw the United Kingdom have an outbreak, and there had to be a tough decision made, do we extend that to the United Kingdom? Were you part of that decision?

A. I was.

Q. And do you agree with that decision as well?

A. I do.

Q. Did that decision save lives?

A. Yes, it did.[1098]

In 2024, Dr. Fauci repeated his support for the travel restrictions believing that they afforded the country time to prepare for the full impact of the virus.

Dr. Anthony Fauci (January 9, 2024)

[1098] The Urgent Need for a National Plan to Contain the Coronavirus: Hearing Before the Select Subcomm. on the Coronavirus Pandemic of the Comm. on Oversight and Reform, 116th Cong. 2, (July 31, 2020).

Q. Dr. Fauci, in your opinion, are travel restrictions a good public health tool?

A. It's context and circumstance dependence, and it depends on what's -- in general. I'm talking generically. I'm not talking about your question. It depends on at what stage of the outbreak you do it. It depends on the level of the particular infection in question that is already in your country. It depends on the efficiency of the transmissibility of a particular infection, because if you have people in your country that are already infected and it's highly transmissible, it doesn't make a lot of sense to restrict. But in a very, very precise period of time when you have virtually nothing in there, you may want to have a temporary restriction to give you time to prepare. That's one of the things that we did.

Q. Did you agree with the President's decision to restrict travel from China?

A. I did, and I said there were caveats to restrictions. I agreed with it, but I said that we've got to be careful because sometimes when you do restrictions they have negative consequences in that you don't have open access to help or even information. But fundamentally I agreed at that time, since we had almost no infections that we knew of in our country, that at least a temporary restriction would be important.

Q. Did you also agree with the EU travel restriction?

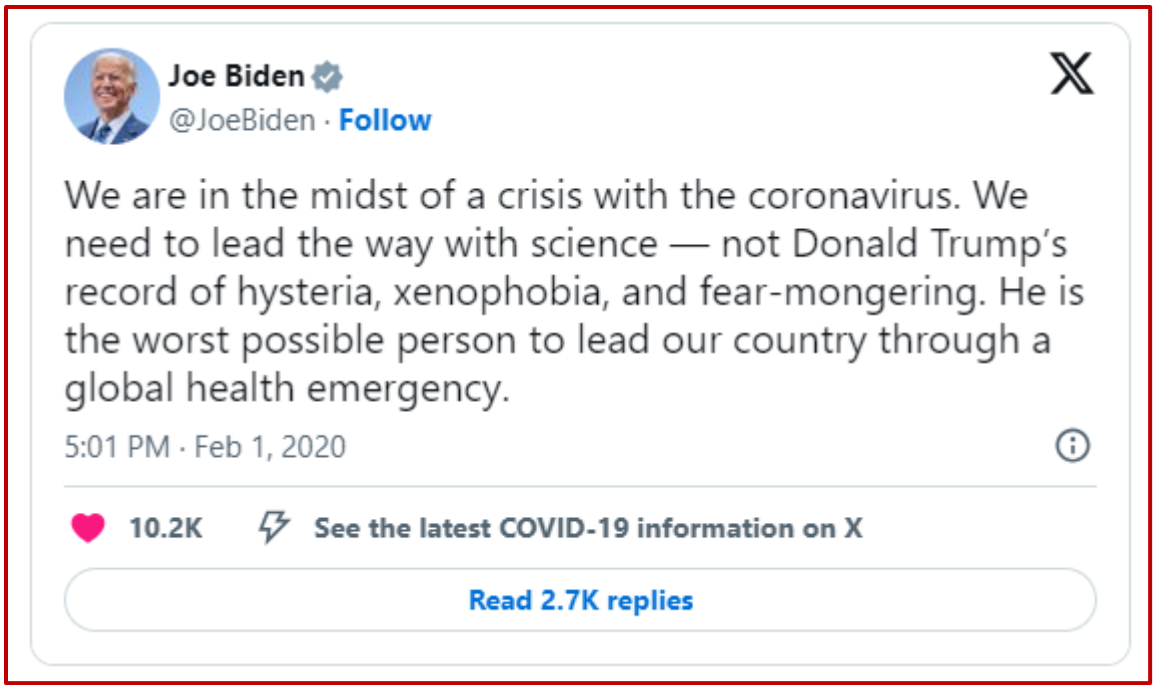
A. I agreed with the suggestion that that be done, yes.

Q. Did you agree with the U.K. travel restriction?

A. Yes, I did.[1099]

Contrary to Dr. Fauci's support, then Presidential Candidate Biden criticized these early travel restrictions as xenophobic.[1100] [1101]

[1099] Fauci TI 2, *supra* note 81, at 125-126.
[1100] Joe Biden (@JoeBiden), Twitter (Feb. 1, 2020) *available at* https://x.com/JoeBiden/status/1223727977361338370.
[1101] Joe Biden (@JoeBiden), Twitter (Mar. 12, 2020) *available at* https://x.com/JoeBiden/status/1238254697695326209.


Joe Biden
@JoeBiden · Follow
We are in the midst of a crisis with the coronavirus. We need to lead the way with science — not Donald Trump's record of hysteria, xenophobia, and fear-mongering. He is the worst possible person to lead our country through a global health emergency.
5:01 PM · Feb 1, 2020
10.2K
See the latest COVID-19 information on X
Read 2.7K replies

Joe Biden
@JoeBiden · Follow
A wall will not stop the coronavirus.
Banning all travel from Europe — or any other part of the world — will not stop it.
This disease could impact every nation and any person on the planet — and we need a plan to combat it.
8:05 PM · Mar 12, 2020
47.3K
See the latest COVID-19 information on X
Read 14.7K replies

While Dr. Fauci voiced his support of the travel restrictions to Congress in 2020 and 2024, he did not publicly voice his support for them with then Presidential candidate Biden, then Speaker Pelosi, and others characterized the travel restrictions as xenophobic. Furthermore, once in office, President Biden enacted similar travel restrictions on travel from several African

countries in late 2021 in response to the Omicron variant of the virus.[1102] At that time, President Biden was not accused of xenophobia or racism for this action, nor should he have been. Similarly, President Trump should not have been criticized for actions supported by public health officials.

In the early days of the pandemic, before widespread community transmission, most COVID-19 cases in the U.S. were associated with international travel. By restricting travel from high-risk areas such as China and Europe, the Trump Administration was able to reduce the influx of infected individuals and save lives.

FINDING:	But for the Chinese Communist Party Blatantly Downplaying and Lying Concerning the Serious Threat Posed by COVID-19, Travel Restrictions Would Have Been Imposed Earlier and Been More Effective.

Undoubtedly, the timing of travel restrictions played a primary role in their effectiveness. Logically, the earlier the travel restrictions are implemented the chance of them being more effective increases. The China travel restrictions were implemented on January 31, 2020, when the virus was still primarily concentrated in China. While some critics argued that these restrictions were ineffective because they should have been implemented earlier, it is important to note that the U.S. was one of the first countries to take such a step.[1103] In contrast, many other countries waited until the virus had already spread internationally before imposing similar restrictions.

Critics of the Trump Administration's travel restrictions argue that they were reactive rather than proactive and that domestic measures such as improved testing and contact tracing would have been more effective in controlling the spread of COVID-19. However, these criticisms fail to acknowledge the absence of widespread testing and domestic preparedness in the early days of the pandemic, leaving travel restrictions as one of the few tools available to slow COVID-19's spread.

It is important to acknowledge that the U.S. was facing an unprecedented public health crisis with limited information about the virus at the time the travel bans were enacted. The goal of these measures was not to stop COVID-19 entirely, but to delay its spread and allow for a more coordinated domestic response.

The travel restrictions could have been more effective had they been enacted earlier, but the responsibility that they were not implemented in early January 2020 or perhaps even in December 2019 lies squarely on the CCP's shoulders. Rather than notifying the WHO and the international community of the alarming viral outbreak, CCP authorities censored and concealed

[1102] Andrew Mark Miller, *Flashback: Biden suggested Trump's coronavirus travel ban was 'xenophobic'*, FOX NEWS (Nov. 26, 2021).
[1103] Nahae Kahg & Beomsoo Kim, *The Effects of Border Shutdowns on the Spread of COVID-19*, JOURNAL OF PREVENTATIVE MEDICINE AND PUBLIC HEALTH (Aug. 30, 2020) (The U.S. travel restrictions for persons from China was announced on January 31, 2020, but implemented and enforced on February 2, 2020. Only Kuwait (January 31, 2020) and Australia (February 1, 2020) implemented their restrictions earlier.).

information and silenced doctors who tried to warn others in the scientific community.[1104] A charitable review of the known timeline of events that unfolded in China indicates that CCP officials should have signaled the international community of an outbreak of concern before Christmas in 2019.[1105] The CCP's desire to hide details and outright lie to the U.S. and other world leaders, immeasurably and unnecessarily cost additional American lives and resources. At the time, the U.S. and WHO had no ability to know the CCP lied about having the virus under control.

The Trump Administration's travel restrictions targeting Asia and Europe during the early days of the COVID-19 pandemic were effective in delaying the spread of the virus into the U.S. While these measures did not and were not designed to completely prevent the introduction of COVID-19, they significantly slowed its transmission and provided critical time for U.S. public health officials to respond. Data supports the argument that these travel restrictions reduced the number of imported cases and helped mitigate the initial impact of the pandemic, buying the U.S. critical time. While no single measure can fully contain a pandemic, the evidence suggests that travel restrictions, when implemented early and in conjunction with other public health strategies, can play an important role in controlling the spread of infectious diseases.

[1104] Annie Sparrow, *The Chinese Government's Cover-Up Killed Health Care Workers Worldwide: Bad advice based on false information led to fatal mistakes*, FOREIGN POLICY (Mar. 18, 2021).
[1105] Jim Geraghty, *The Comprehensive Timeline of China's COVID-19 Lies*, NATIONAL REVIEW (Mar. 23, 2020) ("December 21: Wuhan doctors begin to notice a 'cluster of pneumonia cases with an unknown cause' and December 25: Chinese medical staff in two hospitals in Wuhan are suspected of contracting viral pneumonia and are quarantined. This is additional strong evidence of human-to-human transmission.").

X. Government Perpetrated COVID-19 Misinformation

It has been widely discussed that the COVID-19 pandemic brought with it a new and pervasive wave of misinformation throughout the U.S. and the world. Social media provided fertile ground for accidental falsehoods and deliberate lies to burgeon into the public consciousness.[1106]

Unfortunately, kneejerk reactions by the federal government did little to fix the problem and instead may have sowed deeper distrust of government institutions while trampling on the First Amendment of the Constitution. At times, the government's attempts to quell misinformation contradictorily resulted in new misinformation being spread.

FINDING:	Public Health Officials Incorrectly Characterized the Lab-Leak Theory as a "Conspiracy Theory."

During the early months of the pandemic, Dr. Fauci played a critical role in disparaging the lab-leak theory. Dr. Fauci appeared alongside Dr. Daszak on an episode of former Speaker of the House Newt Gingrich's podcast, *Newt's World*.[1107] During the podcast, Speaker Gingrich asked if Dr. Fauci had heard about the "urban legend" that COVID-19 escaped from a "biological warfare center in Wuhan."[1108] Dr. Fauci told him that these were "conspiracy theories without any scientific basis for it."[1109]

Dr. Anthony Fauci (February 9, 2020)

Q. I don't know if you have had access to enough information from the Chinese, but as you know, there's a sort of urban legend that there's a biological warfare center in Wuhan and that the coronavirus escaped from that. Did you have any sense of where it probably came from.

A. Well, I think ultimately we know that these things come from an animal reservoir. I've heard these conspiracy theories, and like all conspiracy theories, Newt, they're just conspiracy theories. Is it impossible that that could have happened? I don't think I can say that it's not impossible. But I think if you examine all of the isolates and look at the very detailed pattern or map of their molecular structure, you may get more insight as to whether it was a natural direct jump, whether it percolated in another species from the bat to whatever, a civic cat or some other animal, and then jumped species into humans. I think the more you examine isolates and the more we get information, we'll be able to clarify the evolutionary origin of the

[1106] Tiffany Hsu, *As Covid-19 Continues to Spread, So Does Misinformation About It*, THE N.Y. TIMES (Dec. 28, 2022).
[1107] Newt's World: China's Coronavirus, Gingrich 360 (Feb. 9, 2020).
[1108] *Id.*
[1109] *Id.*

virus. But right now, I think the things you're hearing are still in the realm of conspiracy theories without any scientific basis for it.[1110]

Dr. Fauci was also directly involved in the drafting and promotion of Proximal Origin, in which the authors concluded "we do not believe that any type of laboratory-based scenario is plausible."[1111] Evidence suggests that Dr. Fauci "prompted" the drafting of the Proximal Origin paper to "disprove" the lab-leak theory.[1112] Since its publication on March 18, 2020, Proximal Origin has been accessed nearly 6 million times and has been cited countless times to discredit the possibility of a lab leak.[1113] This paper was perhaps the most consequential tool used to paint the lab-leak theory as a conspiracy theory.

Over the course of the Select Subcommittee's investigation, Dr. Fauci repeatedly tried to walk back his assertion that the lab-leak theory was a conspiracy. When asked during a transcribed interview, he acknowledged that the lab leak "isn't inherently a conspiracy theory" but also claimed that instead some people have "made conspiracy aspects from it."[1114]

Dr. Anthony Fauci (January 9, 2024)

Q. Just you sitting here today, do you think the possibility or the hypothesis that the coronavirus emerged from a laboratory accident is a conspiracy theory?

A. Well, it's a possibility. I think people have made conspiracy aspects from it. And I think you have to separate the two when you keep an open mind, that it could be a lab leak or it could be a natural occurrence. I've mentioned in this committee that I believe the evidence that I've seen weighs my opinion towards one, which is a natural occurrence, but I still leave an open mind. So I think that in and of itself isn't inherently a conspiracy theory, but some people spin off things from that that are kind of crazy.[1115]

Similarly, during a public hearing before the Select Subcommittee, Dr. Fauci testified that he did not believe the "concept of there being a lab leak is inherently a conspiracy theory" but that some "distortions on that particular subject" are.[1116]

Dr. Anthony Fauci (June 3, 2024)

[1110] *Id.*
[1111] Proximal Origin, *supra* note 42.
[1112] Memorandum from Select Subcomm. on the Coronavirus Pandemic Majority Staff to Select Subcomm. on the Coronavirus Pandemic Majority Staff, *New Evidence Resulting from the Select Subcommittee's Investigation into the Origins of COVID-19* (Mar. 5, 2023).
[1113] Proximal Origin, *supra* note 42.
[1114] Fauci TI 2, *supra* note 81, at 116
[1115] *Id.*
[1116] Fauci Hearing, *supra* note 231, at 52.

> Q. I just want to clarify for the record, because today you testified that you did not suppress the lab leak theory, yet in the past you have said, quote, "It is a distortion of reality," unquote. You've said, quote, "I've heard these conspiracy theories, and, like all conspiracy theories, they're just conspiracy theories." That's what you told the American people. And so would you like to clarify, what science were you following then versus now?
>
> A. Yeah. No, I -- actually, I've also been very, very clear and said multiple times that I don't think the concept of there being a lab leak is inherently a conspiracy theory. What is conspiracy is the kind of distortions of that particular subject. Like, it was a lab leak, and I was parachuted into the CIA like Jason Bourne and told the CIA that they should really not --
>
> Q. Okay.
>
> A. -- be talking about a lab leak.[1117]

Yet, in Dr. Fauci's Memoir—which was published just weeks after the hearing—Dr. Fauci argued that allegations that EcoHealth's subgrant at the WIV could have caused the COVID-19 pandemic are conspiracy theories.

> The smear campaign soon boiled over into conspiracy theories. One of the most appalling examples of this was the allegation, without a shred of evidence, that a NIAID grant to EcoHealth Alliance (EHA) with a sub-grant to the Wuhan Institute of Virology (WIV) in China funded research that caused the COVID pandemic.[1118]

Later in his memoir, Dr. Fauci wrote:

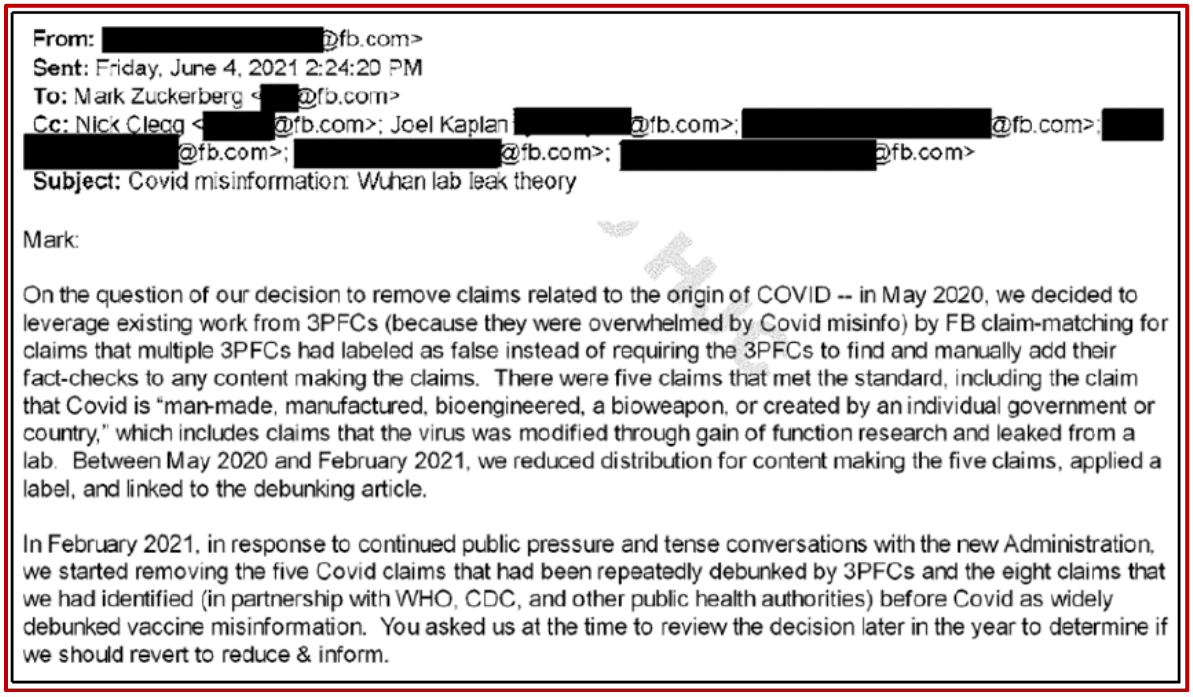
> We cannot account for all the research that takes place in Wuhan or in the rest of China. That is why, as I have often stated publicly, we must keep an open mind to the origin of COVID, as I do.[1119]

Although Dr. Fauci believed the lab-leak theory to be a conspiracy theory at the start of the pandemic, it now appears that his position is that he does have an open mind about the origin of the virus—so long as it does not implicate EcoHealth Alliance, and by extension himself and NIAID. Understandably, as he signed off on the EcoHealth Alliance grant.

FINDING: The Biden Administration Employed Undemocratic and Likely Unconstitutional Methods to Fight What It Deemed to Be Misinformation.

[1117] *Id.*
[1118] Anthony Fauci, On Call: A Doctor's Journey in Public Service, at 418 (Penguin Random House 2024).
[1119] *Id*. at 423.

On May 1, 2024, the House Committee on the Judiciary's Select Subcommittee on the Weaponization of the Federal Government released an Interim Staff Report [hereinafter "Weaponization Report"], which highlighted some of the most egregious examples of the Biden White House's censorship campaign.[1120] The Judiciary Report found that major technology companies Meta, Alphabet, and Amazon changed their content moderation policies in response to pressure from the Biden White House.[1121] For example, the report highlighted emails sent by Mr. Zuckerberg which indicated that pressure from the White House led Facebook to take down posts which claimed that COVID-19 was "man-made, manufactured, bioengineered, a bioweapon, or created by an individual government or country, which includes claims that the virus was modified through gain of function research and leaked from a lab."[1122]



From: [redacted]@fb.com>
Sent: Friday, June 4, 2021 2:24:20 PM
To: Mark Zuckerberg <[redacted]@fb.com>
Cc: Nick Clegg <[redacted]@fb.com>; Joel Kaplan [redacted]@fb.com>; [redacted]@fb.com>; [redacted]@fb.com>; [redacted]@fb.com>; [redacted]@fb.com>
Subject: Covid misinformation: Wuhan lab leak theory

Mark:

On the question of our decision to remove claims related to the origin of COVID -- in May 2020, we decided to leverage existing work from 3PFCs (because they were overwhelmed by Covid misinfo) by FB claim-matching for claims that multiple 3PFCs had labeled as false instead of requiring the 3PFCs to find and manually add their fact-checks to any content making the claims. There were five claims that met the standard, including the claim that Covid is "man-made, manufactured, bioengineered, a bioweapon, or created by an individual government or country," which includes claims that the virus was modified through gain of function research and leaked from a lab. Between May 2020 and February 2021, we reduced distribution for content making the five claims, applied a label, and linked to the debunking article.

In February 2021, in response to continued public pressure and tense conversations with the new Administration, we started removing the five Covid claims that had been repeatedly debunked by 3PFCs and the eight claims that we had identified (in partnership with WHO, CDC, and other public health authorities) before Covid as widely debunked vaccine misinformation. You asked us at the time to review the decision later in the year to determine if we should revert to reduce & inform.

In an August 26, 2024 letter to House Committee on the Judiciary Chairman Mr. Jim Jordan, Mr. Zuckerberg wrote that the Biden Administration "repeatedly pressured our teams for months to censor certain COVID-19 content, including humor and satire, and expressed a lot of frustration when our teams didn't agree."[1123]

[1120] SELECT SUBCOMM. ON THE WEAPONIZATION OF THE FED. GOV'T, H. COMM. ON THE JUDICIARY, INTERIM STAFF REPORT, THE CENSORSHIP-INDUSTRIAL COMPLEX: HOW TOP BIDEN WHITE HOUSE OFFICIALS COERCED BIG TECH TO CENSOR AMERICANS, TRUE INFORMATION, AND CRITICS OF THE BIDEN ADMINISTRATION (May 1, 2024) [hereinafter "Weaponization Report"].
[1121] *Id.*
[1122] *Id.* at 12
[1123] Letter from Mark Zuckerberg, Chairman & CEO, Meta Platforms, Inc., to Jim Jordan, Chairman, H. of Representatives Judiciary Comm. (Aug. 26, 2024).

1 Hacker Way
Menlo Park, CA 94025
United States

August 26, 2024

The Honorable Jim Jordan
Chairman
Committee on the Judiciary
United States House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Chairman Jordan:

I appreciate the Committee's interest in content moderation on online platforms. As you are aware, Meta has produced thousands of documents as part of your investigation and made a dozen employees available for transcribed interviews. Further to our cooperation with your investigation, I welcome the opportunity to share what I've taken away from this process.

* * *

There's a lot of talk right now around how the U.S. government interacts with companies like Meta, and I want to be clear about our position. Our platforms are for everyone -- we're about promoting speech and helping people connect in a safe and secure way. As part of this, we regularly hear from governments around the world and others with various concerns around public discourse and public safety.

In 2021, senior officials from the Biden Administration, including the White House, repeatedly pressured our teams for months to censor certain COVID-19 content, including humor and satire, and expressed a lot of frustration with our teams when we didn't agree. Ultimately, it was our decision whether or not to take content down, and we own our decisions, including COVID-19-related changes we made to our enforcement in the wake of this pressure. I believe the government pressure was wrong, and I regret that we were not more outspoken about it. I also think we made some choices that, with the benefit of hindsight and new information, we wouldn't make today. Like I said to our teams at the time, I feel strongly that we should not compromise our content standards due to pressure from any Administration in either direction -- and we're ready to push back if something like this happens again.

In a separate situation, the FBI warned us about a potential Russian disinformation operation about the Biden family and Burisma in the lead up to the 2020 election. That fall, when we saw a *New York Post* story reporting on corruption allegations involving then-Democratic presidential nominee Joe Biden's family, we sent that story to fact-checkers for review and temporarily demoted it while waiting for a reply. It's since been made clear that the reporting was not Russian disinformation, and in retrospect, we shouldn't have demoted the story. We've changed our policies and processes to make sure this doesn't happen again -- for instance, we no longer temporarily demote things in the U.S. while waiting for fact-checkers.

Apart from content moderation, I want to address the contributions I made during the last presidential cycle to support electoral infrastructure. The idea here was to make sure local election jurisdictions across the country had the resources they needed to help people vote safely during a global pandemic. I made these contributions through the Chan Zuckerberg Initiative. They were designed to be non-partisan -- spread across urban, rural, and suburban communities. Still, despite the analyses I've seen showing otherwise, I know that some people believe this work benefited one party over the other. My goal is to be neutral and not play a role one way or another -- or to even appear to be playing a role. So I don't plan on making a similar contribution this cycle.

Respectfully,

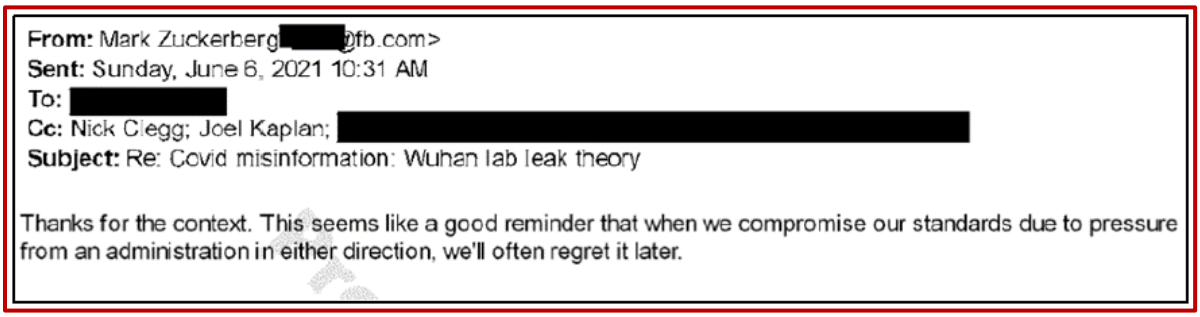
/s/ Mark Zuckerberg

Mark Zuckerberg
Founder, Chairman & CEO
Meta Platforms, Inc.

cc: The Honorable Jerrold Nadler, Ranking Member

Available evidence suggests that a lab leak may be the most likely scenario, but regardless, any assertion that the lab leak is "misinformation" is plainly false—a sentiment which has been shared by numerous federal officials interviewed by the Select Subcommittee, including Dr. Fauci.[1124]

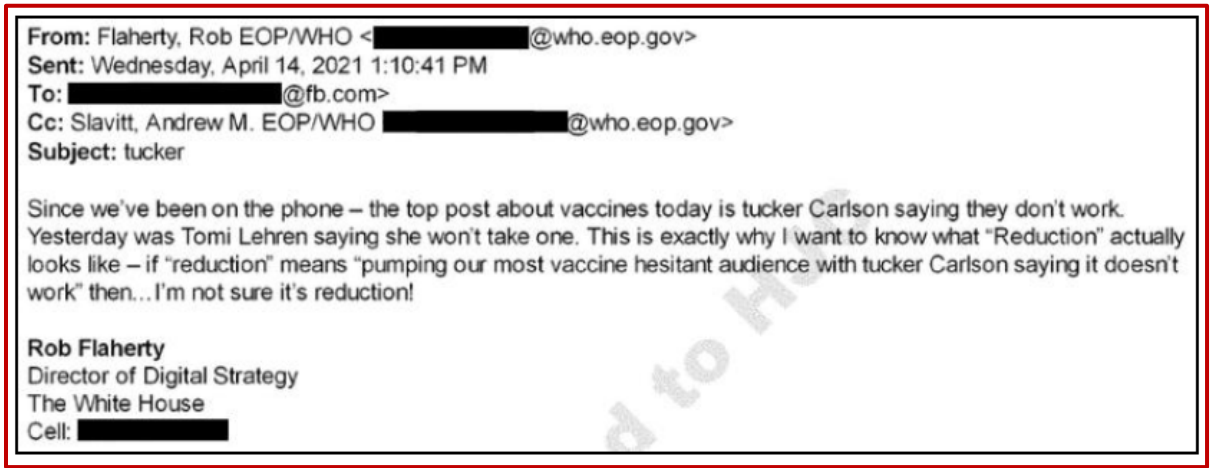
Other emails highlighted in the Judiciary Report illustrate that Mr. Zuckerberg regretted "compromising [Facebook's] standards due to pressure from an administration."[1125]



From: Mark Zuckerberg [redacted]@fb.com>
Sent: Sunday, June 6, 2021 10:31 AM
To: [redacted]
Cc: Nick Clegg; Joel Kaplan; [redacted]
Subject: Re: Covid misinformation: Wuhan lab leak theory

Thanks for the context. This seems like a good reminder that when we compromise our standards due to pressure from an administration in either direction, we'll often regret it later.

The Judiciary Report also highlighted emails indicating that Biden White House officials pressured social media companies to take down or otherwise suppress posts related to other elements of the COVID-19 pandemic, including COVID-19 vaccines and therapeutics. For example, the report includes an email sent by President Biden's Director of Digital Strategy, Mr. Robert Flaherty, pressuring Facebook to reduce posts made by Mr. Tucker Carlson and Ms. Tomi Lahren regarding vaccines.[1126]



From: Flaherty, Rob EOP/WHO <[redacted]@who.eop.gov>
Sent: Wednesday, April 14, 2021 1:10:41 PM
To: [redacted]@fb.com>
Cc: Slavitt, Andrew M. EOP/WHO [redacted]@who.eop.gov>
Subject: tucker

Since we've been on the phone – the top post about vaccines today is tucker Carlson saying they don't work. Yesterday was Tomi Lehren saying she won't take one. This is exactly why I want to know what "Reduction" actually looks like – if "reduction" means "pumping our most vaccine hesitant audience with tucker Carlson saying it doesn't work" then…I'm not sure it's reduction!

Rob Flaherty
Director of Digital Strategy
The White House
Cell: [redacted]

The Judiciary Report also contains numerous other examples of the Biden White House's efforts to suppress content on social media, many of which were originally obtained through litigation brought by state Attorneys General, including Mr. Bailey.[1127] During the Select Subcommittee's June 21, 2023 hearing titled "Churches vs. Casinos: The Constitution is not

[1124] *See generally*, Fauci TI, *supra* note 81.
[1125] Weaponization Report, *supra* note 1120, at 13
[1126] Weaponization Report, *supra* note 1120, at 25
[1127] *See* generally, Weaponization Report.

Suspended in Times of Crisis," Mr. Bailey characterized his efforts to stop the government's suppression of content on social media as "a pitched battle for the very character of our nation."

> This is why Missouri v. Biden is so important. The question of our time is whether Americans will enjoy the legacy of free speech handed down to us by the founding generation and protected by subsequent generations, or whether federal officials will control what we say, what we hear, and how we debate the veracity of claims and arguments. We are locked in a pitched battle for the very character of our nation. If we do not prevail over government officials who seek to control the speech of millions of Americans, we will be left with, in the words of Justice Gorsuch, 'a shell of a democracy and civil liberties just as hollow.'[1128]

FINDING: The Biden Administration and Many Public Health Officials Exaggerated the Power of COVID-19 Vaccines.

COVID-19 vaccines were tremendously important in reducing the severity of COVID-19 symptoms and were extremely effective in doing so.[1129] However, the Biden Administration oversold the power of these vaccines. On more than one occasion, President Biden himself overstated the vaccine's ability to prevent infection and transmission. These false statements likely contributed to Americans' confusion about COVID-19 vaccines and reduced overall vaccine confidence.

President Biden earned a fact check from the *Associated Press* [hereinafter "AP] for a statement which the AP described as "an absolute guarantee…that people who get COVID-19 vaccines are completely protected from infection, sickness, and death from the coronavirus."[1130] Specifically, President Biden said during a July 21, 2021 CNN Town Hall that "[i]f you're vaccinated, you're not going to be hospitalized, you're not going to be in the IC unit, and you're not going to die."[1131] According to the AP's fact checkers, by the time of this statement nearly 5,500 vaccinated people had been hospitalized or died with COVID-19.[1132] As a result, the AP asserted that Biden "[went] too far in assurances on vaccines."[1133]

Similarly, during his announcement of the COVID-19 vaccine mandate for federal workers and contractors on September 9, 2021, President Biden implied that COVID-19 vaccines

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[1128] Churches vs. Casinos: The Constitution is not Suspended in Times of Crisis: Hearing Before Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 1, (June 21, 2023).
[1129] Oliver J. Watson, *Global impact of the first year of COVID-19 vaccination: a mathematical modelling* study, THE LANCET (Sept. 2022).
[1130] Calvin Woodward & Hope Yen, *AP FACT CHECK: Biden goes too far in assurances on vaccines*, ASSOCIATED PRESS (July 22, 2021).
[1131] Alexandra Jaffe & Aamer Madhani, *Biden says getting vaccinated 'gigantically* important', ASSOCIATED PRESS (July 21, 2021).
[1132] Calvin Woodward & Hope Yen, *supra* note 1130.
[1133] *Id.*

were effective at preventing the spread of the virus when he said, "The bottom line – we're going to protect vaccinated workers from unvaccinated coworkers."[1134]

Other officials also made false or misleading statements about COVID-19 vaccines. On March 29, 2021, during an appearance on the *Rachel Maddow Show*, Dr. Walensky claimed that CDC data indicated that "vaccinated people do not carry the virus, don't get sick, and that it's not just in the clinical trials but it's also in the real-world data."[1135] On April 1, 2021, a CDC spokesperson walked back Dr. Walensky's assertions in a comment to *The New York Times*.

> Dr. Walensky spoke broadly during this interview…It's possible that some people who are fully vaccinated could get Covid-19. The evidence isn't clear whether they can spread the virus to others. We are continuing to evaluate the evidence.[1136]

On May 16, 2021, during an appearance on CBS' *Face the Nation*, Dr. Fauci claimed that vaccinated individuals can go without masks even if they have an asymptomatic case of COVID-19 because "it is very unlikely that a vaccinated person, even if there's a breakthrough infection, would transmit it to someone else."[1137] Dr. Fauci also took it a step further and indicated that vaccinated people become "dead ends" for the virus.

> [T]hat's the reason why we say when you get vaccinated, you not only protect your own health, that of the family, but also you contribute to the community health by preventing the spread of the virus throughout the community. And in other words, you become a dead end to the virus. And when there are a lot of dead ends around, the virus is not going to go anywhere.[1138]

During each of their appearances before the Select Subcommittee, Dr. Walensky and Dr. Fauci half-heartedly defended their earlier statements. Dr. Walensky testified that she was "speaking in generalities."

> **Dr. Rochelle Walensky (June 13, 2023)**
>
> Q. Dr. Walensky, simply yes or no. Does a spokesperson from the CDC going on record and correcting the statements that you made undermine and fracture the confidence in CDC leadership?
>
> A. Dr. Joyce, I know you know that I was speaking in generalities, that we saw data and evidence that was over 90 percent that the vaccines

[1134] Kathryn Watson*, et al., Biden announces COVID-19 vaccine mandates that will affect 100 million Americans*, CBS NEWS (Sept. 10, 2021).
[1135] The Rachel Maddow Show, MSNBC (Mar. 29, 2021).
[1136] Apoorva Mandavilli, *Can Vaccinated People Spread the Virus? We Don't Know, Scientists Say*, THE N.Y. TIMES (Apr. 1, 2021).
[1137] Transcript, Anthony Fauci, *Face the Nation* (May 16, 2021).
[1138] *Id.*

were effective in preventing severe disease and death and in fact, in preventing symptomatic disease. And that once people had been vaccinated, even if they were to get infected, they were not getting sick and they were not able to transmit to others, so that was the information.[1139]

Dr. Fauci argued that it "is a complicated issue" and that the vaccines did prevent infection and transmission "in the beginning."

Dr. Anthony Fauci (June 3, 2024)

Q. Did the COVID vaccine stop transmission of the virus?

A. That is a complicated issue, because, in the beginning, the first iteration of the vaccines did have an effect—not 100 percent, not a high effect—they did prevent infection and, subsequently, obviously, transmission. However, it's important to point out, something that we did not know early on that became evident as the months went by is that the durability of protection against infection, and hence, transmission was relatively limited, whereas the duration of protection against severe disease, hospitalization, and deaths was more prolonged. We did not know that in the beginning. In the beginning, it was felt that, in fact, it did prevent infection and, thus, transmission, but that was proven, as time went by, to not be a durable effect.[1140]

Dr. Fauci said that it was "not a durable effect," therefore acknowledging that the vaccines did not effectively prevent the spread of the virus' later variants.[1141] However, even with the most charitable read of the contemporary data supporting these statements, it appears these were gross overstatements of the COVID-19 vaccines' protective abilities, even against the earlier variants.[1142] Perhaps conveniently, the CDC stopped tracking all breakthrough infections beginning May 1, 2021, and instead only tracked breakthrough cases that led to hospitalization or death.[1143] The CDC argued that this decision would help "maximize the quality of the data collected on cases of greatest clinical and public health importance."[1144] The CDC's final report showing breakthrough infections indicated that 10,262 infections had occurred across 46 U.S. states.[1145]

[1139] Oversight of CDC Policies and Decisions During the COVID-19 Pandemic: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, , 118th Cong. 1, at 23 (June 13, 2023).
[1140] Fauci Hearing, *supra* note 231, at 15
[1141] *Id.*
[1142] Apoorva Mandavilli, *Can Vaccinated People Spread the Virus? We Don't Know, Scientists Say.,* THE N.Y. TIMES (Apr. 1, 2021).
[1143] CDC COVID-19 Vaccine Breakthrough Case Investigations Team, *COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021*, MMWR (May 28, 2021).
[1144] Rachel Roubein & David Lim, *CDC under fire for decision to limit tracking of Covid-19 cases in vaccinated people,* POLITICO (July 30, 2021).
[1145] CDC COVID-19 Vaccine Breakthrough Case Investigations Team, *supra* note 1143.

With the outbreak of the Delta variant beginning around July 2021, it became obvious that any mild protection the vaccine may have provided against infection and transmission was significantly diminished. This first emerged with data reported from Barnstable County, Massachusetts after a COVID-19 outbreak following Independence Day celebrations.[1146] A CDC study found that three-quarters of the 469 cases were in fully vaccinated individuals.[1147] The CDC then decided to reverse course and returned to recommending masking regardless of an individual's vaccination status in many areas.[1148] According to CNN, a source involved with the decision process indicated that:

> New unpublished data showing that vaccinated people infected with the Delta coronavirus variant can have as much virus as those who are unvaccinated is the primary driver for the CDC's latest mask guidance change.[1149]

As the Delta variant continued to spread throughout the U.S., this became clear to most Americans as breakthrough infections became commonplace. Ironically, President Biden, Dr. Walensky, and Dr. Fauci, along with numerous other fully vaccinated public figures, reported testing positive for COVID-19 during variant outbreaks, despite being fully vaccinated and boosted.[1150]

The Biden Administration's exaggeration of the COVID-19 vaccine's ability to prevent infection and transmission of COVID-19 may have contributed to Americans' waning trust in vaccines overall.[1151] It is likely that many Americans, especially those who were young and healthy, elected to be vaccinated under the pretense that it would ensure they would not get their loved ones sick. When these pretenses turned out to be false, Americans were understandably upset. This may have also contributed to the lackluster numbers of individuals who elected to receive subsequent booster doses. An October 2023 study, published in the journal *Vaccine*, studied the reasons for why less than 20 percent of eligible Americans had obtained a bivalent booster dose.[1152] According to the study's findings, 23.1 percent of respondents indicated their reason for not getting the booster included that they believed it wouldn't protect them from being infected.[1153]

[1146] Katie Brace*, et al., New Provincetown COVID Cases 'Overwhelmingly' in Vaccinated: Town Manager*, NBC BOSTON (July 12, 2021).
[1147] Catherine M. Brown, *et al., Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021*, MMWR (Aug. 6, 2021).
[1148] Jacqueline Howard, CDC updates guidance, recommends vaccinated people wear masks indoors in certain areas, CNN (July 27, 2021).
[1149] *Id.*
[1150] Jamie Gumbrecht & Jen Christensen, *Fauci tests positive for Covid-19*, CNN (June 15, 2022); Media Statement, CDC, *CDC Director Tests Positive For COVID-19* (Oct. 22, 2022); Maegan Vazquez, *et al., Biden tests positive for Covid-19 and is experiencing mild symptoms*, CNN (July 21, 2022).
[1151] *Public trust in vaccines shows a dip*, NATURE INDIA (May 8, 2024).
[1152] Elizabeth T. Jacobs, *et al., Understanding low COVID-19 booster uptake among US adults*, VACCINE (Oct. 6, 2023).
[1153] *Id.*

FINDING: The U.S. Food and Drug Administration and Other Public Health Officials Falsely Implied that Ivermectin Was Only for Horses and Cows.

Throughout the pandemic, in the face of a deadly disease for which there were minimal treatments available, many doctors explored the use of drugs which were already approved for other indications.[1154] This practice is called "off-label use" and is commonplace in the medical profession. This situation yielded one of the most egregious examples of the Biden Administration's purveyance of misinformation—the FDA's infamous statement which implied that Ivermectin was a veterinary drug for horses and cows and not for humans.[1155] Specifically, the FDA tweeted on August 21, 2021, from its official Twitter (now X) account, "You are not a horse. You are not a cow. Seriously, y'all. Stop it."[1156] Which seemingly conflated the off-label prescription of Ivermectin as being the same as humans intentionally taking the veterinary version of the drug without a doctor.

U.S. FDA
@US_FDA
You are not a horse. You are not a cow. Seriously, y'all. Stop it.
fda.gov
Why You Should Not Use Ivermectin to Treat or Prevent COVID-19
Using the Drug ivermectin to treat COVID-19 can be dangerous and even lethal. The FDA has not approved the drug for that purpose.
7:57 AM · Aug 21, 2021

Ivermectin is FDA approved to treat certain parasites in human and any implication that it is only for "horses" or "cows" is plainly false.[1157]

[1154] *Off-label use of medicines for COVID-19*, WORLD HEALTH ORG., *available at* https://www.who.int/news-room/commentaries/detail/off-label-use-of-medicines-for-covid-19.
[1155] U.S. FDA (@US_FDA), Twitter (Aug. 21, 2021) (Tweet has since been deleted.).
[1156] *Id.*
[1157] *Ivermectin and COVID-19*, U.S. FOOD & DRUG ADMIN. (last updated Apr. 5, 2024) *available at* https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19.

The Development of Vaccines and Treatments, and the Development and Implementation of Vaccination Policies for Federal Employees and Members of the Armed Forces

I. The Success of Operation Warp Speed

OWS was a $10 billion dollar strategy developed and initiated by the Trump Administration during the early months of the COVID-19 pandemic which aimed to expedite the development of a safe and effective vaccine and have substantial quantities available by January 2021.[1158] OWS consisted of a partnership between HHS, DOD, and the private sector and employed several time-saving strategies, while mitigating financial risk through the backing of the federal government. Ultimately, the first COVID-19 vaccine was authorized on December 11, 2020, just less than 7 months after OWS was announced.[1159]

The primary mechanisms OWS leveraged to accelerate the development of COVID-19 vaccines was allowing vaccine companies to start large-scale manufacturing during clinical trials and combining clinical trial phases or running them concurrently, while limiting liability.[1160] This differs significantly from the traditional timeline for vaccine development which tends to be more rigidly sequential.[1161]

OWS' also provided a range of potential options by supporting vaccines with varying characteristics rather than putting all eggs in one basket. Specifically, OWS initially planned to include mRNA, replication-defective live-vector, recombinant-subunit-adjuvanted protein, and attenuated replicating live vector platforms and ultimately supported six vaccine candidates which used three platforms.[1162] Once the vaccine was developed, OWS utilized existing logistics and shipping providers through a strong public-private partnership to ensure rapid distribution.[1163]

FINDING: Operation Warp Speed Was a Great Success and Helped Save Millions of Lives.

Before 2020 the fastest vaccine development took four years.[1164] OWS yielded a vaccine that was available to millions of Americans in less than one year.[1165] By nearly all accounts, this was an incredible feat of science which was made possible by the unique structure of OWS. Dr. Fauci, though reluctant to give credit to the Trump Administration, characterized the effort as

[1158] Release, U.S. Dep't of Defense, Trump Administration Announces Framework and Leadership for 'Operation Warp Speed' (May 15, 2020).
[1159] News Release, U.S. Food & Drug Administration, FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020).
[1160] GAO (GAO-21-319) OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT STATUS AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGES (Feb. 2021) [hereinafter "GAO, Operation Warp Speed"].
[1161] *Id.*
[1162] *Id.*
[1163] From the Factory to the Frontlines The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine, U.S. DEP'T OF HEALTH & HUMAN SERVICES (Sept. 16, 2020).
[1164] Sandy Cohen, *The fastest vaccine in history*, UCLA HEALTH (Dec. 10, 2020).
[1165] GAO, Operation Warp Speed, *supra* note 1160.

"the best decision [he's] ever made with regard to an intervention as director of the institute."[1166] Dr. Fauci also testified that OWS was a "great success."

Dr. Anthony Fauci (January 9, 2024)

Q. Do you think that kind of thought process could be scaled to other pharmaceuticals?

A. I think it can. I mean, I don't think anybody would argue that Operation Warp Speed was a great success. No doubt about that. I think an Operation Warp Speed-like approach could be applied – and, I guess, when you talk about lessons learned for other diseases, it could be applied to other diseases.[1167]

In January 2021, critics argued that the failure to meet the goal of vaccinating 20 million people by the end of 2021 was an indication that OWS was broadly faltering.[1168] However, there is little doubt that the rapid development and authorization of COVID-19 vaccines saved millions of lives.[1169] The NIH estimates that as many as 140,000 American lives were saved by May 2021—within 5 months of the first authorization.[1170]

During a transcribed interview, Dr. Woodcock, definitively agreed that OWS was a success and should be emulated again.

Dr. Janet Woodcock (May 13, 2024)

Q. In your opinion, do you believe Operation Warp Speed was a success?

A. Yes.[1171]

Dr. Woodcock also suggested that during a future pandemic an OWS-like strategy could potentially be even more powerful if the U.S. had better clinical trial infrastructure in order to yield more actionable data for vaccines and therapeutics.

Dr. Janet Woodcock (May 13, 2024)

[1166] Jackie Salo, *Fauci claims credit for COVID vaccines: 'Best decision I've ever made'*, N.Y. POST (Mar. 29, 2021).
[1167] Fauci TI 2, *supra* note 81, at 192.
[1168] Dan Diamond, *The crash landing of 'Operation Warp Speed'*, POLITICO (Jan. 17, 2021).
[1169] Meagan C. Fitzpatrick, *et al., Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths*, THE COMMONWEALTH FUND (Dec. 13, 2022).
[1170] Erin Bryant, *Vaccines prevented up to 140,000 COVID-19 deaths in U.S.*, NIH RESEARCH MATTERS (Aug. 24, 2021).
[1171] Transcribed Interview of Janet Woodcock, M.D., Former Principal Deputy Commissioner, U.S. Food & Drug Admin. at 35 (May 13, 2024) [hereinafter "Woodcock TI"].

Q. Do you think anything should be done differently in a future pandemic, with regard to Operation Warp Speed?

A. I am certainly on record saying that it has more to do with the clinical trial infrastructure. In fact, that we really don't have a sort of – more base for clinical trials in the United States. This was very evident for therapeutics. And there were hundreds and hundreds of trials that went on, I published on this, none of which were able to – would yield any actionable data. On the vaccine side, the companies ended up running the trials because they had the infrastructure to get that done, you know, with the help of the government and the participation of government sites as well.

Q. So you're saying we need a little bit more infrastructure on the therapeutic side to generate good data?

A. On both sides. And I have certainly, as I said, published on this and been very vocal about it.[1172]

FINDING: Then Presidential candidate Joe Biden and Vice-Presidential candidate Kamala Harris May Have Contributed to Early Distrust of Operation Warp Speed and COVID-19 Vaccines.

During the leadup to the 2020 Presidential election, then Vice Presidential candidate, Harris, became one of the first officials to publicly politicize OWS when she suggested that President Trump would "suppress," "muzzle," and "sideline" public health experts because President Trump was "looking at an election coming up in less than 60 days, and um, and he's grasping for whatever he can get to pretend he has been a leader on this issue when he has not."[1173] Harris also refused to definitively say whether she would get a vaccine if they were authorized or approved prior to election day, saying, "[w]ell, I think that's going to be an issue for all of us."[1174] Meanwhile, then Presidential candidate Biden argued that the American people had lost confidence in the Trump Administration, saying, "why do we think the public is gonna line up to be willing to take the injection?"[1175]

It should be obvious to anyone who lived through these events that this was a thinly veiled attempt to politicize the development of COVID-19 vaccines to hurt President Trump's chances in the 2020 election. It was grossly irresponsible to, without any evidence, question the safety and efficacy of COVID-19 vaccinations at that critical juncture in OWS and in the pandemic. These irresponsible statements eventually proved to be outright hypocrisy less than a

[1172] Woodcock TI, *supra* note 1171, at 35.
[1173] Evan Semones*, Harris says she wouldn't trust Trump on any vaccine released before election*, POLITICO (Sept. 5, 2020).
[1174] *Id.*
[1175] *Id.*

year later when the Biden-Harris Administration began to boldly decry all individuals who decided to forgo COVID-19 vaccinations for personal, religious, or medical reasons.[1176]

[1176] *Id.*

II. The Decision to Override the Advisory Committee on Immunization Practices

America's bureaucratic arrangement for studying, regulating and recommending vaccines involves several agencies including NIH, FDA, and CDC. Each agency has advisory committees which consist of experts who evaluate available data, and vote on recommendations. The FDA's VRBPAC is an independent advisory body consisting of 15 voting members who provide recommendations to the FDA Commissioner.[1177] These recommendations are nonbinding but are used by the Commissioner to inform regulatory decisions about biological products such as vaccines.

Similarly, the CDC's ACIP is an independent advisory body that consists of 15 voting members who "develop recommendations on the use of vaccines in the civilian population of the United States."[1178] According to its charter, ACIP provides "advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases."[1179] The decisions made by ACIP are not legally binding, yet, prior to September 2021, it appears that the CDC Director had only ever rejected a recommendation made by ACIP once.

FINDING:	The Biden Administration Arbitrarily and Without Scientific Support Announced COVID-19 Vaccine Boosters Would be Available to All Americans.

Before any official recommendations had been made by the FDA, CDC, or their advisory panels, President Biden began promising that boosters for all Americans were coming soon. On August 18, 2021, President Biden, along with the CDC and FDA, announced a plan to offer booster shots for all Americans beginning the week of September 20.[1180] They noted that the plan was dependent on final evaluation from the FDA and recommendations from the CDC's ACIP. However, they also noted that boosters would be available to "many health care providers, nursing home residents, and other seniors."[1181] These statements are interesting given the fact that Dr. Walensky ultimately ignored her own ACIP to make the boosters available to more workers, including in healthcare. It is also concerning that the Biden Administration chose to announce a specific timeline for this plan when the FDA had not yet made a regulatory decision.

Dr. Woodcock testified to the Select Subcommittee that future FDA regulatory actions are generally considered to be market moving information that should not be made public.[1182]

[1177] *Vaccines and Related Biological Products Advisory Committee*, U.S. FOOD & DRUG ADMIN. (last updated Apr. 26, 2019) *available at* https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee.

[1178] *General Committee-Related Information*, ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (last updated Sept. 10, 2024) *available at* https://www.cdc.gov/acip/about/?CDC_AAref_Val=https://www.cdc.gov/vaccines/acip/committee/index.html.

[1179] Charter of the Advisory Committee on Immunization Practices, U.S. DEP'T OF HEALTH AND HUMAN SERVICES (Filing date Apr. 1, 2024).

[1180] New Release, Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots, U.S. Food and Drug Administration (Aug. 18, 2021); Release, FACT SHEET: President Biden to Announce New Actions to Protect Americans from COVID-19 and Help State and Local Leaders Fight the Virus, The White House (Aug. 18, 2021).

[1181] *Id.*

[1182] *See generally*, Woodcock TI, *supra* note 1171.

When Select Subcommittee staff raised the concern with the announcement of the booster plan, Dr. Woodcock testified that sharing this sort of information was unusual for the FDA, but that it was explainable because of the public health emergency, because the announcement caveated that it was dependent on FDA and CDC review, and because it was not a decision on the approval of a new molecular entity.

Dr. Janet Woodcock (May 13, 2024)

Q. …[W]ithin our earlier conversation about sharing these expected deadlines outside of the FDA, would you say that this announcement falls within the general guidelines of what kinds of information can be shared outside the FDA?

A. Well, again, as I said, it's caveated about the week of September 20th. It's not about an approval, it's about potentially an approval but not of a new molecular entity. It's about yet another dose, more of the same, so to speak. So it's a little less vague than what usually FDA would do, but yet this is within the public health emergency.[1183]

It is important context to consider that these events were during the same period that the FDA was in the final review of the BLA for the primary series of Pfizer's COVID-19 vaccine – wherein senior FDA scientists raised significant concerns about the hasty timelines that were being imposed by their superiors. In this Report, the Select Subcommittee illustrated how this process may have been tainted with political pressure. Some of these very same FDA scientists expressed concern again with the booster authorization process.

On August 31, 2021, *The New York Times* published an article announcing that Dr. Gruber and Dr. Krause were departing the FDA at the end of the following month.[1184] Dr. Gruber and Dr. Krause were "upset about the Biden administration's recent announcement that adults should get a coronavirus booster vaccination eight months after they received their second shot," that "neither believed there was enough data to justify offering booster shots yet," and that they "viewed the announcement, amplified by President Biden, as pressure on the F.D.A. to quickly authorize them."[1185]

On September 13, 2021, Dr. Gruber and Dr. Krause, along with 16 other scientists, wrote an article which in the in *The Lancet* titled, "Considerations in boosting COVID-19 vaccine immune responses."[1186] The article raised concerns about introducing boosters for the general population too soon, especially given the potential risks of immune-mediated side-effects like

[1183] Woodcock TI, *supra* note 1171, at 103.
[1184] Noah Weiland & Sharon LaFraniere, *Two Top F.D.A. Vaccine Regulators Are Set to Depart During a Crucial Period*, THE N.Y. TIMES (Aug. 31, 2021).
[1185] *Id.*
[1186] Philip R. Krause, *et al., Considerations in boosting COVID-19 vaccine immune responses,* THE LANCET (Sept. 13, 2021).

myocarditis.[1187] The authors argued, "[i]f unnecessary boosting causes significant adverse reactions, there could be implications for vaccine acceptance that go beyond COVID-19 vaccines. Thus, widespread boosting should be undertaken only if there is clear evidence that it is appropriate."[1188] They also argued that the available evidence does not seem to suggest a need for boosting the general population since the efficacy of the primary series remained high against severe disease.

> Current evidence does not, therefore, appear to show a need for boosting in the general population, in which efficacy against severe disease remains high. Even if humoral immunity appears to wane, reductions in neutralising antibody titre do not necessarily predict reductions in vaccine efficacy over time, and reductions in vaccine efficacy against mild disease do not necessarily predict reductions in the (typically higher) efficacy against severe disease.[1189]

The Select Subcommittee's investigation confirmed that senior FDA officials were aware of Dr. Gruber's and Dr. Krause's concerns with COVID-19 boosters, but it appears they were not taken very seriously. During a transcribed interview, Dr. Woodcock testified that she knew about the existence of Dr. Gruber's and Dr. Krause's article, but that she had never read it because she "did not feel the need to read their argument."

> **Dr. Janet Woodcock (May 13, 2024)**
>
> Q. Do you recall [the Lancet article]?
>
> A. I knew it was published. I never read it.
>
> ***
>
> Q. You mentioned you had not read this article. Was there a particular reason you had not read it, or was it just you didn't – you had a lot to do?
>
> A. At the time, I was very well aware of all the data, and including data from other countries about the use of boosters and the impact, and so forth. So I did not feel – I know these folks, and I did not feel the need to read their argument.[1190]

Dr. Woodcock also attempted to excuse herself for having ignored the article by claiming that, based on her cursory first-glance while sitting for her transcribed interview, the paper was discussing the "general population" and that the booster "was not indicated in the general population" at the time of the first authorization in September 2021.

[1187] *Id.*
[1188] *Id.*
[1189] *Id.*
[1190] Woodcock TI, *supra* note 1171, at 105.

Dr. Janet Woodcock (May 13, 2024)

Q. Had you heard this sort of concern raised from within FDA prior to September 13, 2021, when this article was published? Similar, meaning concerns that the evidence may not or does not show the need for widespread use of booster vaccination in populations that have received an effective primary regimen?

A. Well, first of all, if I may.

Q. Certainly.

A. They are talking about general population. This wasn't indicated -- the booster at the time of approval was not indicated in the general population. So you might say they were arguing against something that didn't happen.[1191]

Dr. Woodcock's excuse is not supported by the facts. While Dr. Gruber and Dr. Krause argued against the need for boosting the "general population" at that time, it is incorrect to assert that their arguments are therefore irrelevant. The core of their argument is that due to insufficient evidence supporting the necessity of boosters, they should be limited to the most vulnerable first, and remaining doses—since they are identical to the primary series doses—should be used to vaccinate those who had remained unvaccinated entirely.

Yet, Dr. Woodcock, herself, endorsed President Biden's plan to begin boosting all adults by September 20.[1192] An *NBC* article from September discussing VRBPAC's September 17 votes pointed out how President Biden's plan could be imparting pressure on the FDA to make the boosters available to all adults.

> Still, the decision could put the FDA at odds with Biden administration officials who have been pushing to begin giving out booster shots to the general population starting the week of Sept. 20, essentially starting the countdown for the FDA and the CDC to act.[1193]

On the same day that the FDA authorized the booster for a limited population, President Biden doubled down on his premature promises by publicly stating that they would soon be made available to all adults.[1194] Additionally, the FDA's and Dr. Walensky's decisions to recommend boosters for workers in supposedly high risk occupations necessarily included

[1191] Woodcock TI, *supra* note 1171, at 105-106.
[1192] New Release, U.S. Food & Drug Admin., Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots (Aug. 18, 2021).
[1193] Sara G. Miller, *et al., FDA advisory group rejects Covid boosters for most, limits to high-risk groups*, NBC NEWS (Sept. 17, 2021).
[1194] Jonathan Wolfe, *Coronavirus Briefing: What Happened Today*, THE N.Y. TIMES (Sept. 24, 2021).

millions of young, healthy workers for whom the marginal benefit of a booster was, according to the arguments made by Dr. Gruber and Dr. Krause, likely very low.[1195]

FINDING:	U.S. Centers for Disease Control and Prevention Director Rochelle Walensky Overruled Expert Advisors in an Apparent Attempt to Satisfy President Joe Biden's Arbitrary Vaccine Approval Goals.

On September 17, 2021, VRBPAC convened a public meeting to evaluate the use of Pfizer's primary series COVID-19 vaccine as booster doses for those who had already received the primary series. The panel voted against making a recommendation for the broad population, but recommended FDA authorize boosters for Americans aged 65 and up, those aged 18 to 64 who were at high risk for severe illness, as well as those in certain high-risk occupations.[1196] On September 22, 2021, FDA announced an amended EUA for booster doses in the same populations recommended by VRBPAC.[1197]

On September 23, 2021, ACIP convened its public meeting on the same topic.[1198] The ACIP concurred with FDA's recommendation for a COVID-19 vaccine booster for Americans 65 and older and aged 18 to 64 who were at high risk for serious illness.[1199] However, departing from the FDA in a 6-9 vote, ACIP specifically ruled against a broad recommendation for workers in higher risk professions including health care workers and teachers.[1200]

On September 24, 2021, in a decision deemed "highly unusual," Dr. Walensky overruled ACIP's recommendation and issued updated CDC guidance that fully concurred with FDA.[1201] Dr. Walensky characterized her announcement of new CDC guidance simply as an endorsement of ACIP's recommendations. However, she completely skipped over the fact that she had overruled her own agency's advisory committee on the key aspect of boosting workers in high-risk professions.

> Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations and also recommended a booster dose for those in high risk occupational and institutional settings.[1202]

[1195] *Id.*
[1196] *Center for Biologics Evaluation and Research, Summary Minutes*, FOOD & DRUG ADMIN. (Sept. 17, 2021) *available at* https://www.fda.gov/media/152597/download.
[1197] News Release, FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations, U.S. Food & Drug Administration (Sept. 22, 2021).
[1198] Melissa Mahtani & Meg Wagner, *The latest on Covid-19 and vaccine boosters*, CNN (Sept. 23, 2021).
[1199] Meeting of the Advisory Committee on Immunization Practices (ACIP), Summary Minutes (Sept. 22-23, 2021, Publish date: Nov. 4, 2021) *available at* https://stacks.cdc.gov/view/cdc/114944.
[1200] *Id.*
[1201] Apoorva Mandavilli & Benjamin Mueller, *C.D.C. Chief Overrules Agency Panel and Recommends Pfizer-BioNTech Boosters for Workers at Risk*, THE N.Y. TIMES (Sept. 24, 2021).
[1202] Press Release, CDC Statement on ACIP Booster Recommendations, Centers for Disease Control and Prevention (Sept. 24, 2021).

During ACIP's meeting, experts who voted against the measure argued that there was not sufficient data to support the recommendation, that it was too narrow and premature, and that there was little marginal benefit in acting then rather than waiting for better data.[1203] They also said that they felt they were being pulled into an "emotional decision" and that this decision could undermine confidence in the primary vaccine series.

> Ms. Bahta said she felt like they were being pulled into an emotional decision. The science shows that this is a very effective vaccine. This decision was made for the vaccinated, not the unvaccinated. She did not believe they had the data in the younger age groups to make a decision for a booster dose. To her, it would suggest that the vaccine does not work. While they know this is not true, that is likely how that message will be conveyed to the broader public. That was why she voted "not" for the third and fourth interim recommendations.[1204]
>
> Dr. Bell agreed with everything Dr. Bahta said in explaining why she voted "no" and also to emphasize that this represented the beginning of a lot of activity around booster doses and other vaccination efforts that are forthcoming. In this situation, at this moment, and given the lack of evidence about the marginal benefits of booster doses for people in certain groups who received a Pfizer primary series, it was too narrow and too soon. In terms of the potential risks for adverse outcomes of waiting until more is known, there was little marginal benefit to making this booster dose available at this time in her opinion given all of the unknowns.[1205]

Reportedly, Dr. Walensky's decision to break with the recommendations of the ACIP came as a surprise to some of her own staff.[1206] According to reports, it was understood that "[h]ours before [Walensky's] statement, agency insiders predicted she would stick with the usual protocol because doing otherwise would undermine the process and upset the advisers as well as her own staff."[1207]

During ACIP's meeting, prior to the votes, Dr. Walensky spoke directly to ACIP members, saying, "[k]now that I am grateful for your efforts and that I so appreciate your expertise, your counsel, and your partnership."[1208] Unfortunately, it appears that Dr. Walensky may not have meant what she said given that she flagrantly ignored ACIP's expertise and counsel on this key decision.

[1203] *Id.*
[1204] ACIP Summary Minutes, *supra* note 1199, at 92. Meeting of the Advisory Committee on Immunization Practices (ACIP), Summary Minutes (Sept. 22-23, 2021, Publish date: Nov. 4, 2021) available at https://stacks.cdc.gov/view/cdc/114944.
[1205] *Id.*
[1206] Apoorva Mandavilli & Benjamin Mueller, *supra* note 1201.
[1207] *Id.*
[1208] *Id.*

II. The Review of Pfizer's Biologics License Application

COVID-19 vaccines were novel in many ways, including that they were widely distributed under EUA before they received full approval from the FDA. Specifically, the first COVID-19 vaccine was administered under EUA on December 11, 2020, and the first vaccine received full approval on August 23, 2021.[1209] During the course of this 255-day period, more than 360 million doses of COVID-19 vaccines were distributed throughout the U.S.[1210] Since the FDA first established its EUA program in 2004, the anthrax vaccine was the only other vaccine to receive an EUA and this vaccine was only administered to an extremely limited cohort of people. [1211]

Throughout the early rollout of COVID-19 vaccinations in the winter and spring of 2021, there was an aggressive and widespread campaign—often with the support of government public health institutions—to convince the American people to get vaccinated. However, the nuances of the vaccines' regulatory status were unclear to most regular people. Instead, these novel mRNA vaccines were dubbed simply as "safe and effective," with very little opportunity for patients to discuss these vaccines with their doctor and assess their individual risks and benefits.

In actuality, the FDA's standards for EUA differ from their standards for approving a BLA. Most importantly, for a BLA to be approved a product must demonstrate that it is safe and effective, whereas for an EUA to be authorized the product must only demonstrate that it may be safe and effective.[1212] The decision to widely distribute COVID-19 vaccines under an EUA likely had significant negative effects on the public's perceptions of the vaccines. It appears that some FDA officials shared this concern as it was later used as a justification for why the review of the BLA was aggressively accelerated.

On May 18, 2021, Pfizer became the first company to submit a BLA to the FDA for review.[1213] Under normal circumstances, this review would have taken around 12 months and have been completed around May 2022. However, this BLA was given priority review status, which stipulates that the process should be completed in around 8 months, therefore setting an ADD of mid-January 2022. Details provided by Dr. Gruber, and her deputy, Dr. Krause, indicated that high-level FDA officials imparted significant pressure on them to continually accelerate the timeline despite their concerns that safety and efficacy of the vaccines would suffer.

The FDA ultimately accelerated the process substantially, with Pfizer receiving its official approval letter for its COVID-19 vaccine under the brand name COMIRNATY on August 23, 2021 – nearly 5 months faster than the typical priority review timeline.[1214] In September 2021, it

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[1209] New Release, U.S. Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 23, 2021).
[1210] Kanishka Singh, *U.S. administers 361.7 million doses of COVID-19 vaccines -CDC*, REUTERS (Aug. 22, 2021).
[1211] 70 Fed. Reg. 5452 (Feb. 2, 2005).
[1212] Guidance Document, Emergency Use Authorization of Medical Products and Related Authorities, U.S. FOOD & DRUG ADMIN. (Jan. 2017).
[1213] Letter from Mary A. Malarkey, Dir., Office of Compliance and Biologics Quality & Marion F. Gruber, Dir., Offices to Vaccines Research and Review, to Amit Pate, Pfizer Inc. (Aug. 23, 2021) *available at* https://www.fda.gov/media/151710/download.
[1214] *Id.*

became public that Dr. Gruber and Dr. Krause were retiring from the FDA.[1215] Shortly afterwards it was reported that Dr. Gruber's and Dr. Krause's departure was related to their internal disagreement about whether available data supported booster shots for the general public.[1216]

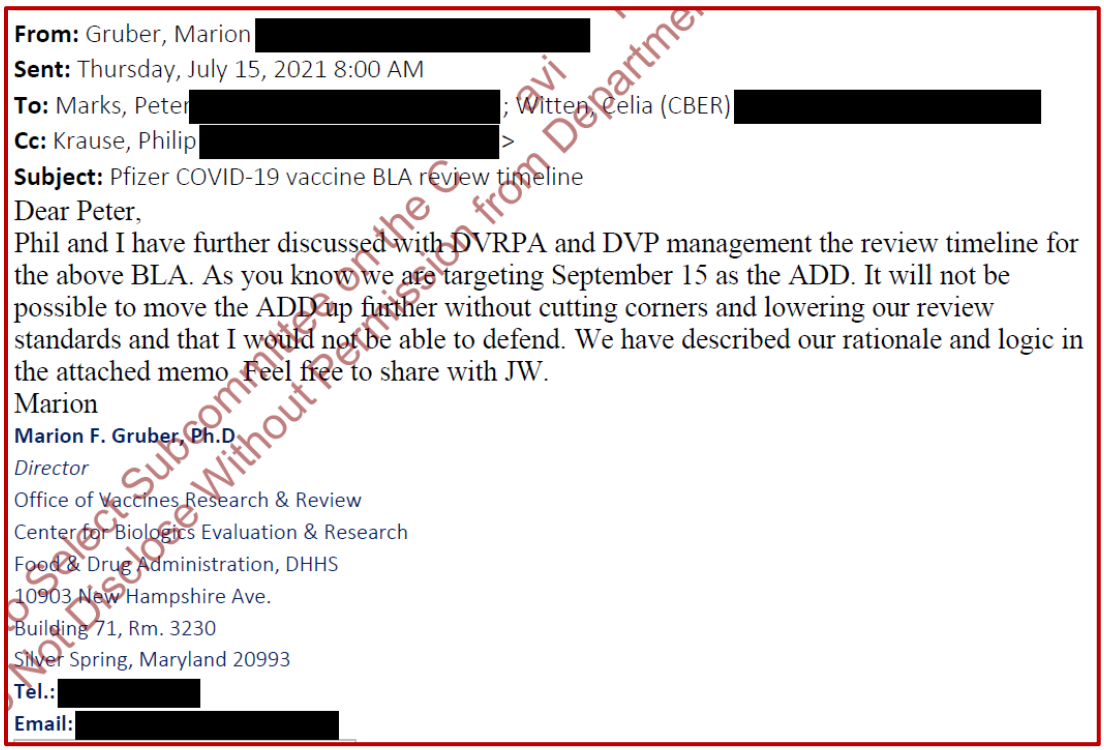
Since then, evidence further indicates that the FDA may have allowed politics to interfere with what should have been dispassionate and scientifically driven regulatory process. Dr. Gruber and Dr. Krause expressed legitimate concerns about the hyper-acceleration of the review of COVID-19 vaccines and booster shots and were ignored. When they detailed these concerns to Dr. Marks he pressured them further.[1217] When the issue was brought to Dr. Woodcock, she placed Dr. Marks in charge and sidelined Dr. Gruber and Dr. Krause.[1218] Unfortunately, the FDA's acceleration of the process may have contributed to the public's waning confidence in vaccines, public health, and government institutions, and possibly to facilitate harmful COVID-19 vaccine mandates.[1219]

FINDING:	The Biden Administration Sidelined Senior Scientists After They Expressed Concern Regarding the Rapid Pace of Review of Pfizer's Biologics Approval Application.

As Director of OVRR, Dr. Gruber was the most senior expert in charge of reviewing BLA's for vaccines, and the ultimate decisionmaker. According to their own testimony, Dr. Gruber, Dr. Krause, and Dr. Marks initially agreed to set the ADD for mid-October 2021.[1220] According to Dr. Krause, Dr. Marks came back soon afterwards and requested it be accelerated to September 15, 2021.[1221] Dr. Gruber and Dr. Krause discussed with their team and told Dr. Marks that it would be possible to compress the review and meet the September 15 deadline.[1222] Not long after that, Dr. Marks approached them yet again and demanded that the timeline be pushed up even earlier than September 15—a target date which was already eight months earlier than the standard review timeline, and four months earlier than the priority review timeline.[1223]

[1215] Dan Diamond, *Two FDA officials who oversee coronavirus vaccine reviews to depart*, THE WASH. POST (Sept. 1, 2021).
[1216] Noah Weiland & Apoorva Mandavilli, *In Review, Top F.D.A. Scientists Question Imminent Need for Booster Shots,* THE N.Y. TIMES (Sept, 13, 2021, updated Oct. 1, 2021).
[1217] E-Mail from Marion Gruber, Ph.D., Dir., Office of Vaccines Research & Review, U.S. Food & Drug Admin, to Peter Marks, FDA Center for Biologics Evaluation and Research (CBER), *et al*., (July 19, 2021, 11:59 AM).
[1218] Woodcock TI, *supra* note 1171, at 79-91
[1219] Elizabeth Williams & Robin Rudowitz, *Headed Back to School in 2024: An Update on Children's Routine Vaccination Trends*, KFF (July 18, 2024).
[1220] SELECT SUBCOMM. ON THE ADMINISTRATIVE STATE, REGULATORY REFORM, AND ANTITRUST OF THE COMM. ON THE JUDICIARY, INTERIM STAFF REPORT, POLITICS, PRIVATE INTERESTS, AND THE BIDEN ADMIN.'S DEVIATION FROM AGENCY REGS. IN THE COVID-19 PANDEMIC, at 85-86 (June 24, 2024) [hereinafter "Judiciary Report"].
[1221] *Id.*
[1222] *Id.*
[1223] *Id.* at 248.

In a July 15, 2021 email from Dr. Gruber to Dr. Marks, she explained that after discussing with her team, she and Dr. Krause believed it would be impossible to accelerate the review any further without "cutting corners."[1224]



From: Gruber, Marion [redacted]
Sent: Thursday, July 15, 2021 8:00 AM
To: Marks, Peter [redacted]; Witten, Celia (CBER) [redacted]
Cc: Krause, Philip [redacted]>
Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,

Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.

Marion

Marion F. Gruber, Ph.D.
Director
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Center for Biologics Evaluation & Research
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10903 New Hampshire Ave.
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Silver Spring, Maryland 20993
Tel.: [redacted]
Email: [redacted]

Select Subcommittee on the C... Not Disclose Without Permission from Departme...

Attached to this email was a memo explaining their logic in more detail.[1225]

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[1224] E-Mail from Marion Gruber, Ph.D., Dir., Office of Vaccines Research & Review, U.S. Food & Drug Admin, to Peter Marks, FDA Center for Biologics Evaluation and Research (CBER) (July 15, 2021, 8:00 AM).
[1225] Internal memo, U.S. FOOD & DRUG ADMIN. (July 15, 2021).

Pfizer COVID-19 STN 125742.0 BLA target AD: 09/15/2021

OVRR's decision to expedite the planned completion of the Pfizer BLA review to September 15, 2021, was based on a careful consideration of the steps that need to take place. OVRR's logic is outlined below.

The Pfizer BLA is a complex BLA

Of note, the pivotal study supporting the BLA was conducted in over 40,000 subjects. To provide additional assurance of the safety and effectiveness of this product that is currently administered to millions of subjects in the US and globally, we requested 6 months safety follow-up to support the BLA as opposed to the 2 months safety follow-up that supported the EUA. The applicant has also submitted additional efficacy data on substantial numbers of cases in vaccine and control groups that were not available with the EUA request submission and data on post-authorization safety experience. These additional data are substantial and enable additional important analyses.

The BLA merits a complete and thorough review

OVRR's reviews of vaccine BLAs, unlike those of regulators in other countries, do not rely on summary tables that are generated by the developer. OVRR views it as essential that review of the safety and efficacy data not only includes an evaluation of the data analyses conducted by the applicant, but also includes CBER's own analysis of the datasets submitted by Pfizer. This has been OVRR's standard for all other BLAs, and while time-consuming, OVRR believes that confidence in COVID vaccines would not be served by starting to cut corners on this review.

While the efficacy data may appear simple to evaluate, longer term follow-up of placebo-controlled data provides essential information that may be of high relevance to discussions about boosting. Moreover, the safety data represent the only placebo-controlled data we have on the safety of this vaccine. These placebo-controlled data are likely to be free of biases that might occur in post-licensure observational studies, so it is imperative to carefully review the reported adverse events, including evaluation of the sponsor's attribution of these events (or lack thereof) to vaccination.

As compared with other BLAs, the proposed completion date of Sept 15 would be unprecedented

The Pfizer COVID-19 BLA received priority designation, allowing 8 months for CBER review and is a "rolling" BLA. Note that the final piece of the roll was received on May 18, 2021 at which point the review clock started. We are targeting September 15, 2021 as the date we will be taking regulatory action, which is less than 4 months from the date the last section of the BLA was submitted. Thus, we will be reviewing this very large and complex BLA in a 1/3 rd of the time typically allowed for a BLA standard application and in less than half the time allocated for a priority review application.

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This is possible only with deprioritization of other reviews, including some related to COVID, and reassignment of work to other experienced medical officers.

At this time, while we have hired additional medical officers, we have a limited number of clinical reviewers with the specialized experience needed to assess complex preventive vaccine files requiring comprehensive review, such as those for COVID vaccines that have progressed to pursuing an EUA or BLA. Addressing the high volume of COVID-related work has necessitated deprioritizing some vaccine files.

In addition, we have de-prioritized certain COVID-vaccine related submissions (including some from Pfizer), e.g., amendments pertaining to protocols and studies in pregnant women and immunocompromised subjects, until such time that the BLA review is completed.

However, Pfizer requested advice on 4 booster protocols and advice on the safety data base to support use of the COVID-19 vaccine in pediatric populations 6 months – 12 years of age. These cannot be deprioritized and will need to be reviewed by staff and overseen by supervisors familiar with the Pfizer COVID vaccine IND ad EUA, concurrent with review activities for the Pfizer COVID-19 BLA.

While it was not possible to completely reassign other COVID-19 vaccine- related and non-COVID vaccine-related review work for the MOs assigned to the Pfizer BLA, workload adjustments have been made to allow them to focus nearly exclusively on review of this BLA.

In addition, if the trajectory of the pandemic/emergence of variant of concerns (i.e., delta variant) necessitates the review of EUA amendments for booster doses for the currently U.S. EUA authorized COVID-19 vaccines, from a public health perspective, these reviews will need to take priority over completing the BLA review by September 15, 2021.

Additional support from outside OVRR will not speed up the review

Review efforts for the Pfizer COVID-19 vaccine BLA in the various disciplines, including CMC, nonclinical, PV and facility is ongoing. Information requests have been sent to Pfizer as part of these reviews, and responses are pending. However, the rate-limiting step in regard to potentially accelerating the review timeline to earlier than September 15 is the clinical review, considering the complexity of the clinical safety and effectiveness data. The safety review encompasses a critical evaluation and interpretation of solicited and unsolicited safety data and SAES, and clinical AEs of interest including, but not limited to, the myocarditis signal that has been observed following the administration of the Pfizer COVID-19 vaccine under EUA. We are also performing subgroup analyses of safety and effectiveness data for race, ethnicity and subjects with underlying conditions. Completion of these reviews may require additional correspondence with the sponsor. We hope that reviewers will be able to complete their detailed review memos for the various review activities by the beginning of September as planned. After this has been finished, there are important additional review activities to be completed, including label

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negotiations, supervisory review, SBRA preparation, etc. such that it would not be possible to issue the license until September 15.

The experienced MOs assigned to this file are working closely with the data analytics team in CDER-OCS and staff in CBER/OBE who are supporting their review efforts. The need for coordination of evaluation and consistency within the review would lead to diminishing returns if additional staff would be added to this effort. In addition, the reviews have already been initiated and sections of the review are being written as they are completed. Other sections depend on the reviews of the earlier sections, so those parts of the review cannot be completed until the earlier parts of the review have been done, and because they need to take the subtleties of the earlier parts into account, cannot as reliably be performed by medical officers who are new to the file. Thus, assigning additional MOs (even if experienced) to assist in review of the Pfizer COVID vaccine BLA, it is likely that the review effort would be will delayed rather than expedited the review effort as these reassigned individuals would need to familiarize themselves with the file.

Furthermore, reassignment of experienced medical officers to the Pfizer BLA would lead to a cascade of further reassignments and their own assignments will be delayed ultimately leading to an increase in back-log including critical ongoing review activities to support:

- Many anticipated several BLA submissions in in 3/4Q of 2021 including the BLAs for the [redacted] and BLAs for [redacted] all of which are likely to qualify for priority review designation
- The [redacted] BLA,
- Several BLA supplements including an efficacy supplement for [redacted] for the pediatric population,
- Efficacy supplements for [redacted] and
- Booster protocols for the Pfizer, [redacted] COVID EUAs.

In summary, it is not possible to further abbreviate the BLA review timeline for the Pfizer COVID-19 vaccine BLA, our target review date for this file remains September 15, 2021.

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The paragraph headers for this memo provide a succinct summary of their arguments:

- The Pfizer BLA is a complex BLA
- The BLA merits a complete and thorough review
- As compared with other BLAs, the proposed completion date of Sept 15 would be unprecedented
- This is possible only with reprioritization of other reviews, including some related to COVID, and reassignment of work to other experienced medical officers
- Additional support from outside OVRR will not speed up review

- Additional support from outside of OVRR, if effectively used, might reduce the need to deprioritize certain submissions[1226]

Dr. Marks forwarded this email and the attached memo to Dr. Woodcock and suggested that they set up a phone call to discuss the situation.

From: Marks, Peter
To: Woodcock, Janet
Cc: Tierney, Julia
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Date: Thursday, July 15, 2021 10:11:27 AM
Attachments: image001.png
Pfizer COVID-19 vaccine BLA review timeline.docx

Dear Janet,
Perhaps we can have a brief call tomorrow? I can fill you in on the conversation that I had with Marion and Phil subsequent to their sending me this document. I have asked them to provide me with a timeline of milestones, and they are meeting with the review team today to be able to do so tomorrow morning. That said, they are intransigent at this time on the Sept 15 date.
Thanks very much.
Best Regards,
Peter

From: Gruber, Marion [redacted]>
Sent: Thursday, July 15, 2021 8:00 AM
To: Marks, Peter <[redacted]; Witten, Celia (CBER) [redacted]
Cc: Krause, Philip <[redacted]
Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,
Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.
Marion

Marion F. Gruber, Ph.D
Director
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993
Tel.: [redacted]

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Dr. Woodcock replied and indicated her intention to have Dr. Marks take over the review of the Pfizer BLA and replace Dr. Gruber and Dr. Krause.[1227] During her transcribed interview, Dr. Woodcock testified that this decision to replace them was made on her own.

[1226] *Id.*
[1227] E-Mail from Janet Woodcock, Acting FDA Dir. to Peter Marks, CBER Dir. (July 16, 2021, 11:10 AM).

Dr. Janet Woodcock (May 13, 2024)

Q. And you said, "Peter, you can find out more when you take over." Are you referring to Dr. Marks taking over the review from Dr. Gruber?

A. Yes, I believe I was.

Q. So is it fair to say that …[b]y July 16th, you had decided that Dr. Marks would be taking over?

A. That's fair.

***

Q. Did you make that decision on your own?

A. Yes.

Q. And did Dr. Marks request that, or was it your idea?

A. It was my idea.[1228]

On July 19, 2021, Dr. Gruber, Dr. Krause, Dr. Marks, Dr. Woodcock, and her Chief of Staff, Ms. Julia Tierney, convened a meeting to discuss this further. On July 21, 2021, Dr. Gruber sent an email to the group memorializing her perspective of what had been discussed during the meeting.[1229]

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[1228] Woodcock TI, *supra* note 1171, at 80.

[1229] E-Mail from Marion Gruber, Ph.D., Dir., Office of Vaccines Research & Review, U.S. Food & Drug Admin, to Peter Marks, FDA Center for Biologics Evaluation and Research (CBER) (July 19, 2021, 11:59 AM).

From: Gruber, Marion [redacted].gov>
Sent: Wednesday, July 21, 2021 11:59 AM
To: Marks, Peter [redacted]gov>; Woodcock, Janet <[redacted]
Cc: Tierney, Julia <[redacted]; Krause, Philip [redacted]
Subject: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Janet and Peter,

The following summarizes my understanding of the July 19, 2021, 8:30 am meeting held between you, Phil Krause, Julie Tierney and myself to discuss the review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine. During this meeting, I made reference to the memo that Dr. Krause and I composed and sent to Dr. Marks on July 15, 2021, delineating OVRR's rationale for why the review timeline and target action due date, September 15, 2021, for this BLA cannot be compressed further. To recap, that memo stated that the review requires a thorough evaluation and FDA's own analysis of the safety, effectiveness and manufacturing information submitted to support licensure of this vaccine. This has been OVRR's standard for all other BLAs, and while time-consuming, OVRR believes that public confidence in COVID-19 vaccines would not be served by rushing our review and evaluation of the submitted data. In addition, Dr. Krause and I pointed out the very important regulatory issues that still need to be settled by the time we take action on this BLA—including the pediatric plan — which is becoming increasingly complex in light of increasing evidence of association of this vaccine and development of myocarditis (especially in young males, but also ages included in the BLA indication). This also impacts the finalization of post-marketing requirements and post-marketing commitments. In addition, there are pending information requests to the sponsor, and there will likely be additional information requests based on ongoing review of the data, and the timing of the sponsor response is beyond CBER control.

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I reiterated during our meeting that OVRR is targeting September 15, 2021, as the date we will be taking regulatory action, which is less than 4 months from the date the last section of the BLA was submitted. Thus, we will be reviewing this complex BLA with a large amount of data, in a third of the time typically allowed for a BLA standard application and in less than half the time allocated for a priority review application. In response to your questions, I described OVRR's BLA review assignment processes. I emphasized that for this particular BLA, we assigned two experienced medical officers to this file who are working closely with the data analytics team in CDER-OCS and three statisticians from CBER/OBE who are supporting these review efforts. I did not emphasize this during our meeting, but you should also know that our typical review process includes frequent formal and informal communications with managers at all levels and other OVRR experts not directly assigned to the review team. I reiterated that adding staff to this review at this advanced stage would likely slow down the review due to the need to bring new people up to speed. You inquired whether we need additional help and also asked about the expertise of MOs assigned to this file noting that there would be staff in FDA, e.g., pediatric cardiologist that could assist in the review. You expressed concern about the rising COVID-cases in the US and globally, largely caused by the Delta variant and stated your opinion that, absent a license, states cannot require mandatory vaccination and that people hesitant to get an EUA authorized vaccine would be more inclined to get immunized when the product is licensed. You emphasized your interest in licensing this vaccine as soon as possible—a goal that we agree with. We too are concerned about the rising COVID-19 cases in the US, however, our concern is that a review that is hyper-accelerated beyond the already very rapid September 15 target date and as a consequence, may be less thorough than our typical review seems more likely to undermine confidence in the vaccine (and, indeed, in FDA's credibility) than to increase it.

You informed us of your decision that OVRR management and oversight of the BLA review will be delegated to Dr. Marks who will provide you with weekly updates on the review process and ensure that due diligence is exercised while I am away [redacted] You also informed me that Dr. Krause will not be involved in the BLA oversight as he will be overseeing other regulatory and programmatic programs in OVRR. I expressed my disagreement with these decisions because standard procedures are for the deputy Office Director to assume an Acting Role when the Office Director is out of the Office. I note that Dr. Krause is a recognized expert in vaccine regulation, development and very familiar with the scientific and clinical issues presented by this specific vaccine product and that the review team relies on his expertise and guidance.

I would also like to emphasize OVRR staff's dedication and experience in promoting public health by making safe and effective vaccines available for use in the United States. Since I believe we all agree in the importance both of a rapid decision and a thorough scientific and credible review, Dr. Krause and the OVRR staff will stand ready to assist in any way possible to achieve both of these goals. Please confirm that this summary reflects your recollection of this meeting. If it does not, I would appreciate your letting me know any specific areas where your recollection is different.

Thank you,
Marion

Marion F. Gruber, Ph.D
Director

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Dr. Gruber wrote that she and Dr. Krause remained concerned that:

> [A] review that is hyper-accelerated beyond the already very rapid September 15 target date and as a consequence, may be less thorough than

> our typical review seems more likely to undermine confidence in the vaccine (and, indeed, in FDA's credibility) than to increase it.[1230]

Dr. Gruber also memorialized Dr. Woodcock's decision to have Dr. Marks take over the review from her and Dr. Krause.

> You informed us of your decision that OVRR management and oversight of the BLA review will be delegated to Dr. Marks who will provide you with weekly updates on the review process and ensure that due diligence is exercised while I am away [REDACTED]. You also informed me that Dr. Krause will not be involved in the BLA oversight as he will be overseeing other regulatory and programmatic programs in OVRR. I note that Dr. Krause is a recognized expert in vaccine regulation, development and very familiar with the scientific and clinical issues presented by this specific vaccine product and that the review team relies on his expertise and guidance.[1231]

Dr. Woodcock testified that the rationale she gave during the meeting for sidelining Dr. Gruber and Dr. Krause with Dr. Marks centered around the fact that Dr. Gruber was going to be on vacation out of the country and that Dr. Krause was an expert but not a clinician.

> **Dr. Janet Woodcock (May 13, 2024)**
>
> Q. Do you generally agree with [Dr. Gruber's] summary of the meeting?
>
> A. She's focusing on the timelines. I did not focus on that in my part of the meeting. I focused on the fact that she would be on vacation, which is perfectly reasonable, some family time, out of the country, not in a position to oversee this very complicated, as she said, review. Dr. Krause is an expert, he's not a clinician, and I asked that Peter take over the review.[1232]

During a Select Subcommittee hearing on February 15, 2024, Dr. Marks dismissively testified that, in his view, Dr. Gruber and Dr. Krause's concerns were simply related to "the workload."

> **Dr. Peter Marks (February 15, 2024)**
>
> Q. Do you recall why Dr. Gruber and Dr. Krause expressed concern about accelerating the approval of the vaccine?

[1230] E-Mail from Marion Gruber, Ph.D., Dir., Office of Vaccines Research & Review, U.S. Food & Drug Admin, to Janet Woodcock, *et al.* (July 21, 2021, 11:59 AM).
[1231] *Id.*
[1232] Woodcock TI, *supra* note 1171, at 92.

A. They were concerned about the workload.[1233]

Yet, these explanations seem to leave out the fact that Dr. Gruber and Dr. Krause had become "intransigent" on moving up the ADD any further than September 15, which they explained their expert rationale for in detail, and that neither Dr. Gruber nor Dr. Krause stated they were unable to fulfill their duties.

FINDING: The Biden Administration Accelerated the Approval of Pfizer's Biologics Approval Application to Impose Vaccine Mandates

Dr. Gruber's summary of the July 19 meeting also explicitly highlighted the fact that Dr. Marks and Dr. Woodcock indicated that they wanted to move up the target date in part because it was a prerequisite for vaccine mandates to take effect.

> You expressed concern about the rising COVID-cases in the US and globally, largely caused by the Delta variant and stated [their] opinion that, absent a license, states cannot require mandatory vaccination and that people hesitant to get an EUA authorized vaccine would be more inclined to do so when the product is licensed.[1234]

When confronted with Dr. Gruber's meeting summary, Dr. Woodcock testified that she was unable to recall whether vaccine mandates came up at all during their July 19 meeting.

Dr. Janet Woodcock (May 13, 2024)

Q. Did the topic of vaccine mandates or mandatory vaccination policies come up at all during this meeting?

A. Not by me.

Q. But do you recall that someone else may have brought them up?

A. I do not recall.[1235]

However, she was able to recall that at some undetermined time, Dr. Marks had indeed discussed COVID-19 vaccine mandates, as well as the fact that the regulatory status of COVID-19 vaccines could have an impact on the ability for mandates to be levied.

Dr. Janet Woodcock (May 13, 2024)

[1233] Accessing America's Vaccine Safety Systems, Part 1: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 2, (Feb. 15, 2024) [hereinafter "Accessing America's Vaccine Safety Systems, Part 1"].
[1234] E-Mail from Marion Gruber, Ph.D., Dir., Office of Vaccines Research & Review, U.S. Food & Drug Admin, to Janet Woodcock, *et al.* (July 21, 2021, 11:59 AM).
[1235] Woodcock TI, *supra* note 1171, at 90.

Q. Did any conversations [with Dr. Marks] ever touch on vaccine mandates or mandatory vaccination policies, broadly?

A. I believe Dr. Marks brought it up a couple times.

Q. A couple of times?

A. Yes.

Q. Do you remember specific times?

A. No.

***

Q. Did Dr. Marks ever speak to you about the need for full biologics approval in order for groups to institute vaccine mandates?

A. Dr. Marks commented on the fact that mandates for some populations would be tied to their FDA status.[1236]

During his transcribed interview with the House Committee on the Judiciary, Dr. Marks said that he recalled having some discussions about the link between full BLA approval and vaccine mandates, but that he did not recall bringing up vaccine mandates during the July 19 meeting, or who else may have done so.

Dr. Peter Marks (April 15, 2024)

Q. Was it Janet Woodcock or was it you who told Dr. Gruber that [absent a license, states cannot require mandatory vaccination]?

A. I can't speak to – I don't know. And I don't recall that I would have ever said this, but I can't recall, and I can't speak to who said it.

Q. Were you present when this was said?

A. Again, I can't recall it being said. I was something that had – look, the potential for vaccine mandates is something that may have been discussed over the course of time even from early on in – during the pandemic. But I can't recall who would have introduced this to the conversation.[1237]

[1236] Woodcock TI, *supra* note 1171, at 29.
[1237] Judiciary Report, *supra* note 1220, at 89.

During the Select Subcommittee's February 15, 2024 hearing, Dr. Marks testified indecisively that he didn't recall the specific conversation about vaccine mandates, but that it was probably just a "statement of fact."

Dr. Peter Marks (February 15, 2024)

Q. Do you recall any conversations regarding the need to approve the vaccines in order for it to then be mandated?

A. There was an acknowledgment that an approval could allow vaccine mandates to occur, but they were not conversations over that, that it were –

Q. So Dr. Gruber wrote that you and Dr. Woodcock expressed your opinion that absent a license States cannot require mandatory vaccination. Do you recall this conversation?

A. I don't know what you're referring to, but I -- there is probably -- it's just a statement of fact that that once you have a licensed vaccine, a mandate could be placed.[1238]

Contradictorily to Dr. Marks and Dr. Woodcock, during transcribed interviews with the House Committee on the Judiciary, Dr. Gruber and Dr. Krause both testified unambiguously that it was both Dr. Marks and Dr. Woodcock that expressed their opinion that a license was a prerequisite to vaccine mandates.

Dr. Gruber testified:

Dr. Marion Gruber (July 18, 2023)

Q. Your email is addressed to both Marks and Woodcock, and here you say "you." Was it Woodcock or was it Marks or was it both of them that expressed their opinion that a license would be needed for vaccine mandates?

A. It was both of them. Yeah.[1239]

Dr. Krause testified:

Dr. Philip Krause (September 7, 2023)

Q. Did Dr. Woodcock or Dr. Marks state that the goal was to require mandatory vaccination?

[1238] Accessing America's Vaccine Safety Systems, Part 1, *supra* note 1233.
[1239] Judiciary Report, *supra* note 1220, at 60

A. Well, the, as stated in the email, the discussion was about State mandates, and of course there already had been some mandates announced by the Biden administration. There was a so-called vaccinate-or-test rule that they had put in place at some point earlier in August, as I recall. And so there was no doubt, in my recollection, that Dr. Marks and Dr. Woodcock saw the licensure of the vaccine as a prerequisite to mandates.[1240]

Dr. Gruber and Dr. Krause each also testified that making way for vaccine mandates appeared to have played a key role in Dr. Marks' and Dr. Woodcock's persistence in hyper-accelerating the review of the Pfizer BLA:

Dr. Gruber testified:

Dr. Marion Gruber (July 18, 2023)

Q. Were there other reasons they gave, or could you determine why they had such a sense of urgency to get this?

A. The reason given to me was the vaccine mandate. And the second reason that I also mentioned in my email was that people hesitant to take a vaccine that is authorized but not approved may be inclined to take the vaccine if it's licensed. These were the two reasons provided to me.[1241]

Dr. Krause testified:

Dr. Philip Krause (September 7, 2023)

Q. Now you just said the need to support mandates. In your view, was that need part of why you all were being pressured to meet this deadline, as this assumed date?

A. Given that they brought it up, it's hard to imagine that that was not a component of this pressure.[1242]

It is highly concerning that paving the way for mandatory vaccination policies played any role at all in the FDA's process for approving COVID-19 vaccines, and even worse that it appears to have played a primary role in their rationale for casting aside top vaccine experts and hyper-accelerating the target date. Vaccine mandates are fundamentally highly political matters

[1240] Judiciary Report, *supra* note 1220, TI of Philip Krause, at 288.
[1241] Judiciary Report, *supra* note 1220, TI of Marion Gruber, at 131.
[1242] Judiciary Report, *supra* note 1220, TI of Philip Krause, at 295.

that the FDA should be completely insulated from. Dr. Woodcock readily admitted this fact during her transcribed interview.

> **Dr. Janet Woodcock (May 13, 2024)**
>
> Q. Does the FDA have any role in shaping policies like vaccine mandates?
>
> A. No.[1243]

FINDING: U.S. Food and Drug Administration Officials Refused to Rebut Allegations the Biden White House Was Involved in the Pfizer Biologics Approval Application.

On August 9, 2021, after Dr. Marks had taken over the review of the Pfizer BLA but prior to it being completed, Secretary Austin issued a memo which announced his intention to seek President Biden's approval to mandate COVID-19 vaccines for U.S. servicemembers "no later than mid-September, or immediately upon the U.S. Food and Drug Administration (FDA) licensure, whichever comes first."[1244] As indicated by the memo, Secretary Austin was unable to issue a mandate for COVID-19 vaccines without a waiver from President Biden so long as the vaccines remained under EUA status.[1245] The memo implies that Secretary Austin was aware that the FDA had been working with an ADD of September 15, 2021. Additionally, the DOD's press release announcing this memo denotes that "the Food and Drug Administration is expected to give full approval to the vaccines, possibly by the end of the month."[1246]

Ultimately, the FDA issued its approval for Pfizer's BLA on August 23, 2021, and the very next day, on August 24, 2021, Secretary Austin issued a memo announcing the DOD's vaccine mandate.[1247] The dubious timing raises concerns about whether Secretary Austin, or any other executive branch official, may have been involved in the hyper-acceleration of the ADD. Dr. Krause testified that he thought it appeared that some decisions that OVRR would normally make were being made elsewhere:

> **Dr. Philip Krause (September 7, 2023)**
>
> I admit that the events in July and August surrounding the BLA and the booster vaccines made me concerned, without direct knowledge of any

[1243] Woodcock TI, *supra* note 1171, at 96-97
[1244] Memorandum from Lloyd Austin, Sec'y of Defense, to All Dept's of Defense Employees, *Message to the Force* (Aug. 9, 2021).
[1245] Wen. W. Shen, CONG. RESEARCH SERVS., R46745, *State and Federal Authority to Mandate COVID-19 Vaccination* (May 17, 2022) (in the military context, for instance, additional waiver requirements under 10 U.S.C. § 1107a may apply to the administration of medical products subject to EUAs to servicemembers.)
[1246] Jim Garamone, *Biden to Approve Austin's Request to Make COVID-19 Vaccine Mandatory for Service Members*, DOD NEWS (Aug. 9, 2021).
[1247] Memorandum from Lloyd Austin, Sec'y of Defense, to Senior Pentagon Leadership, Commanders of the Combatant Commanders, Defense Agency and DOD Field Activity Directors, Rescission of August 24, 2021 and November 30, 2021 Coronavirus Disease 2019 Vaccination Requirements for Members of the Armed Forces (Jan. 10, 2023).

specific outside interference, because I didn't know of any communications from the outside, but it appeared as though major decisions that normally would have been within the purview of the office were now being made outside of the office, whether at the center director's level or even elsewhere.[1248]

During the Select Subcommittee's February 15, 2024 hearing, Dr. Marks testified that he had made the decision to pressure Dr. Gruber and Dr. Krause to move up the ADD earlier than September 15th all on his own.

Dr. Peter Marks (February 15, 2024)

Q. Did anyone instruct you, or is this just a decision you made on your own?

A. This was a decision I had made on my own.[1249]

Dr. Woodcock denied that she had any foreknowledge of Secretary Austin's plans to issue a vaccine mandate.

Dr. Janet Woodcock (May 13, 2024)

Q. Were you aware that Secretary Austin was planning to mandate COVID 19 vaccination before August 24th, 2021?

A. No.[1250]

Dr. Woodcock also denied communicating with anyone at DOD about the Pfizer BLA prior to it being approved.

Dr. Janet Woodcock (May 13, 2024)

Q. Did you communicate with anyone at the Department of Defense prior to the BLA being issued regarding the BLA?

A. No.[1251]

However, Dr. Woodcock admitted that she did communicate with the White House about the Pfizer BLA.

Dr. Janet Woodcock (May 13, 2024)

[1248] Judiciary Report, *supra* note 1220, Krause TI, at 303.
[1249] Accessing America's Vaccine Safety Systems, Part 1, *supra* note 1233.
[1250] Woodcock TI, *supra* note 1171, at 99.
[1251] Woodcock TI, *supra* note 1171, at 68.

Q. Did you communicate with anybody at the White House regarding the Pfizer BLA prior to being issued?

A. Yes.[1252]

When pressed for details, Counsel for the Biden Administration instructed Dr. Woodcock not answer questions about her conversations with the White House regarding the ADD for the Pfizer BLA review as it evolved over time.

Dr. Janet Woodcock (May 13, 2024)

Majority Staff. Did you discuss with the White House the expected ADD as it evolved over time for the Pfizer BLA?

HHS Counsel. Now we're getting more into the substance, and at that point, we're not going to be able to answer.

Majority Staff. You're instructing the witness not to answer?

HHS Counsel. Yes.[1253]

Dr. Woodcock also testified that updates about the timing of an ADD for a vaccine approval are typically shared with the CDC, because they have related actions to take, but not other agencies. She explained that this information is considered to be private.

Dr. Janet Woodcock (May 13, 2024)

Q. So as the ADD gets moved around, are you providing updates to CDC about that?

A. Yes.

Q. Do you typically provide -- or does FDA typically provide updates about the ADD to other agencies besides CDC?

A. FDA typically does not do that, because that's market moving information, right? And we ask anybody that we generally wouldn't tell people that, right? But this relationship with CDC is very special, because they have an action to take as well.

Q. So outside of CDC, it's generally private information?

[1252] Woodcock TI, *supra* note 1171, at 68.
[1253] *Id.*

A. Absolutely.[1254]

Dr. Woodcock acknowledged that despite this information being considered private, it would sometimes be reported publicly in the papers.

Dr. Janet Woodcock (May 13, 2024)

Q. [D]uring the COVID vaccine approval process, was the ADD shared with any other agencies?

A. Not to my -- not by me.

Q. To your knowledge, did somebody else?

A. Well, it often would appear in the papers. But that might have been from the companies, because we tell the company, so they can prepare. They have to -- the company has to do a lot of work. It's a very frenetic activity toward the end of that, as you approach that final date. And so the companies would be told. So it's hard to know who would -- but the dates might start floating around out there. You know, companies are talking about that.[1255]

It seems unlikely that neither Dr. Marks nor Dr. Woodcock recall who brought up vaccine mandates during the July 19 meeting, despite recalling many other details about the call and the time around it. It also seems unlikely that Dr. Gruber was mistaken in her very detailed summary—which was sent only two days after the meeting had taken place—and that she and Dr. Krause were both mistaken during their transcribed interviews.

Instead, it appears that Dr. Marks and Dr. Woodcock may have chosen to feign amnesia, or intentionally not answer questions, because they would otherwise be implicated in a pressure campaign to hyper-accelerate the approval of COVID-19 vaccines to facilitate the state and federal vaccine mandates which were predicated on the vaccines' regulatory status. Nonetheless, their testimony directly contradicts that of Dr. Gruber and Dr. Krause and has left unanswered questions about what information the White House or other executive branch agencies were given ahead of the BLA approval.

Ultimately, Dr. Gruber did sign off on the approval of Pfizer's BLA and testified that she believed the vaccine to be safe and effective.[1256] However, this does not excuse the fact that the process that was undertaken was reckless, nor does it undo the public's perception that these vaccines were approved in a hurry to satisfy a political agenda—one that culminated with harmful vaccine mandates which trampled on individual liberty, informed consent, and the doctor-patient relationship. Federal health agencies should have done more to ensure the integrity of the process and preserve the American people's trust in public health and vaccines. In failing

[1254] Woodcock TI, *supra* note 1171, at 25-26.
[1255] *See generally*, Woodcock TI, *supra* note 1171.
[1256] Judiciary Report, supra note 1220, at 120.

to do so, they have likely done irreparable damage to public trust and our pandemic preparedness.

IV. Public Health Officials Disregarded Natural Immunity, Despite Its Proven Effectiveness and Durability

Natural immunity, and infection acquired immunity, is the body's ability to create internal protection against an invading infectious agent.[1257] In the simplest of terms, a protein called an antibody enters the blood stream and helps the body detect and fight the infectious agent if it returns. It is science known and studied since the 1800s.[1258] A common example of this, is varicella, commonly referred to as chickenpox. At least 90 percent of U.S. adults are immune to chickenpox because of having the disease as a child.[1259] In addition to the high rate of infection acquired immunity to the disease, upon license of the vaccine in 1995, the number of cases of chickenpox fell by more than 95 percent.[1260]

FINDING:	Those Who Recovered From COVID-19 Were Conferred Infection Acquired Immunity.

While the novelty and lack of initial knowledge of COVID-19 cannot be understated, there was established science that infection from coronaviruses, including SARs-CoV-1, produced infection acquired immunity.[1261] However, it was not long before global research was presented establishing that COVID-19 did produce a natural immunity after infection.

A study, published in October 2021, examined the rate of COVID-19 reinfection amongst people in Lombardy, Italy during the first wave of infections.[1262] The study suggested reinfection of COVID-19 were rare and those who'd recovered from the virus were at a lower risk of reinfection.[1263] The results further suggested natural immunity provided a protective effect for approximately a year, similar to the reported vaccine studies.[1264] An additional Italian study from March 2020, followed 36 patients with documented cases of the virus.[1265] These patients were followed until September 2021 and the 17 who remained unvaccinated continued to present IgG antibodies through at least 18 months.[1266] Another February 2020 study out of Qatar, and published in the *New England Journal of Medicine*, concluded previous infection of COVID-19 prevented reinfection of the virus.[1267] A January 2021 study, out of La Jolla Institute for Immunology, found 95 percent of the 200 participants presented durable immune responses for

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[1257] Natural Immunity, CLEVELAND CLINIC (last reviewed Aug. 15, 2024).
[1258] Jonathan D. Kaunitz, *The Development of Monoclonal Antibodies*, PUBMED CENTRAL (Apr. 2017).
[1259] *Varicella (Chickenpox): Questions and Answers*, IMMUNIZE.ORG, *available at* https://www.immunize.org/wp-content/uploads/catg.d/p4202.pdf.
[1260] *Id.*
[1261] Jonathan D. Kaunitz, *The Development of Monoclonal Antibodies*, PUBMED CENTRAL (Apr. 2017).
[1262] Jose Vitale, *et al*. *Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy*, PUBMED CENTRAL (May 2021).
[1263] *Id.*
[1264] *Id.*
[1265] Sheena Meredith, *COVID-19: Why Are We Ignoring Infection-Acquired Immunity*?, MEDSCAPE (Feb. 28, 2022).
[1266] Puya Dehgani-Mobaraki*, et al., Long-term persistence of IgG antibodies in recovered COVID-19 individuals at 18 months post-infection and the impact of two-dose BNT162b2 (Pfizer-BioNTech) mRNA vaccination on the antibody response: Analysis using fixed-effects linear regression model*, PUBMED (Dec. 6, 2022).
[1267] Heba N. Altarawneh*, et al., Protection against the Omicron Variant from Previous SARS- CoV-2 Infection*, THE NEW ENGLAND JOURNAL OF MEDICINE (Feb. 9, 2022).

up to eight months after infection of COVID-19.[1268] Additional studies out of England and Israel in 2021 found infection rates at equally low levels amongst those who were fully vaccinated and those who previously were infected COVID-19.[1269]

On February 16, 2023, more than three years into the pandemic, *The Lancet* published a report confirming the benefits associated with naturally acquired immunity.[1270] The study found that a previous COVID-19 infection offers at least the same level of protection as two doses of a high-quality mRNA vaccine, such as Moderna or Pfizer-BioNTech.[1271] Protection from reinfection of the virus may be as high as 40 weeks or longer.[1272] The likelihood of not getting infected again is the strongest with the original (ancestral) strain of the virus, and the alpha, beta, and delta variants, all of which remain at more than 78 percent after 40 weeks.[1273] The omicron variant is lower, at 36.1 percent.[1274] Protection was high across all variants for sever disease (hospitalization or death).[1275]

This study was the first to "comprehensively assess natural immunity protection against COVID-19 reinfection by variant (primary infection and reinfection) and to evaluate waning immunity with time since primary infection."[1276] The researchers considered the severity of symptoms, the variant of the virus, and how long since the subjects last positive COVID-19 test. *The Lancet* article included 65 studies from 19 countries.

Even with all the global scientific data that those who contracted COVID-19 had some extended time of immunity, the Biden Administration and the CDC began pushing a vaccine-only strategy to population immunity. When the vaccines rolled out, approximately 91 million Americans were previously infected with COVID-19.[1277] Yet any status of recently recovered from the virus, and thus provided with a short time of immunity, was completely ignored.

FINDING:	Herd Immunity is a Real Concept and Occurrence Supported by Public Health Leaders, Such as Dr. Fauci, and There Was a Coordinated Effort from Public Health Officials to Ignore Natural Immunity and Suppress Dissenting Opinions.

The very initial phases of the COVID-19 pandemic were understandably riddled with unknowns. Yet, while research and information were gathered, the science supported infection from coronaviruses, including SARS-CoV-1, provided individuals with infection acquired

[1268] Sharon Reynolds, *Lasting Immunity Found After Recovery From COVID-19*, NATIONAL INSTITUTES OF HEALTH (Jan. 26, 2021).
[1269] *See*, Victoria Hall, *et al., SARS-CoV-2 Infection Rates of Antibody-Positive Compared With Antibody-Negative Health-care Workers in England: a Large, Multicenter, Prospective Cohort Study*, THE LANCET (2021); Yair Goldberg, *et al. Protection of Previous SARS-CoV-2 Infection is Similar to that of BNT162b2 Vaccine Protection: A Three Month Nationwide Experience from Israel*, AMERICAN JOURNAL OF EPIDEMIOLOGY (Apr. 24, 2021).
[1270] Caroline Stein, *Past SARS-CoV-2 infection protection against re-infection: a systematic review and meta-analysis*, THE LANCET (Feb. 16, 2023; updated: Mar. 11, 2023).
[1271] *Id*.
[1272] *Id.*
[1273] *Id.*
[1274] *Id.*
[1275] *Id.*
[1276] *Id.*
[1277] *Id.*

immunity.[1278] Many researchers recognized the existing science and called for policy makers and government officials to use infection acquired immunity from COVID-19 to help control the spread of virus. Many countries around the world allowed a previous COVID-19 infection to satisfy the individuals "vaccination status."[1279] Yet U.S. public health officials resisted including infection acquired immunity when developing guidance and policy during the pandemic. Despite this resistance, in a transcribed interview, Dr. Fauci testified that natural immunity is a "real thing."

Dr. Anthony Fauci (January 9, 2024)

Q. I want to talk about natural immunity for a minute. In general, is natural immunity a real thing?

***

A. It's a real thing.[1280]

The lack of policy conversations was evident when other ideas were proposed, but never discussed. For example, the Great Barrington Declaration was an open letter published in October 2020 in response to mass lockdowns.[1281] Originally signed by scientists from the University of Oxford, Stanford University, and Harvard University, the document presented the idea that lockdowns had adverse effects on both the mental and physical health of populations.[1282] It called for a "focused protection" pandemic strategy.[1283] The authors proposed reducing the harms of lockdown by ending the mandatory restrictions for most people, yet still protecting those most vulnerable.[1284]

Critics of this idea immediately disqualified the proposal, to an unsettling degree never seen before in the scientific community. Anyone associated with the paper was immediately categorized as a "fringe" theorist.[1285] Rather than being allowed to engage in scientific and political debate, the alternative proposal was dubbed dangerous and referred to as a "let it rip," meaning the vast spread of the virus, approach. The Great Barrington Declaration categorically did not advocate for individuals to intentionally get infected with COVID-19 or a "let it rip" approach. It was evident from the early days of the COVID-19 pandemic that public health leadership had little interest in engaging in any form of alternative debate.

[1278] Li-Ping Wu, *et al., Duration of Antibody Responses After Severe Acute Respiratory Syndrome*, PUBMED CENTRAL (Oct. 2007).
[1279] *Id.*
[1280] Fauci TI 2, *supra* note 81, at 209.
[1281] Dr. Martin Kulldorff, *et al*., THE GREAT BARRINGTON DECLARATION (Oct. 4, 2020) [hereinafter "Great Barrington Declaration"].
[1282] *Id.*
[1283] *Id.*
[1284] *Id.*
[1285] The Editorial Board, *How Fauci and Collins Shut Down Covid Debate*, WALL STREET JOURNAL (Dec. 21, 2021).

In an October 8, 2020, email from Dr. Collins to Dr. Fauci, Dr. Lane, and Dr. Tabak, Dr. Collins wrote that the proposal of a policy other than national lockdowns needed "a quick and devastating published take down of its premise."[1286]

One week after this e-mail, Dr. Collins called The Great Barrington Declaration "a fringe component of epidemiology…that is not mainstream science."[1287] He also called it outright dangerous.[1288] Following the sharp rebuke from NIH officials, reputable and international media outlets, such as *Wired*, *The Wall Street Journal*, *The Guardian*, *Independent*, and *Telegraph*, amongst almost all others, began dismissing the idea that the Great Barrington Declaration was something to be taken seriously or even discussed.[1289]

The Biden Administration was also complicit in attempting to manage the flow of information on COVID-19 in public spaces. In an August 2024 letter to the House Committee on the Judiciary, Mr. Zuckerberg wrote that the White House pressured the company to censor certain posts about COVID-19.[1290]

This kind of rhetoric and behavior created a scientific environment that fostered hostility and outright contempt for differing opinions. Scientists and doctors were demonized by colleagues and peers within their own community.[1291] Even though it was evident this virus was novel, there was absolutely no room for any kind of high level, scientific debate.

The authors of the Great Barrington Declaration, and any other scientists with a different idea than what was dictated by public health officials, were not demanding their policy ideas become law. They were simply asking that they be allowed to participate in the conversation. Yet infection acquired immunity was never part of the national public health policy during the coronavirus pandemic.

The job of public health officials is to offer the best scientific advice to protect the nation as a whole. Yet during the COVID-19 pandemic, many public health leaders narrowly focused on one mission, to the detriment of others, including the trust of the public. In July 2023 at a panel for Braver Angels, Dr. Collins reflected on his time as a leader during the pandemic.

> If you're a public-health person and you're trying to make a decision, you have this very narrow view of what the right decision is, and that is something that will save a life…so you attach infinite value to stopping the disease and saving a life. You attach a zero value to whether this actually totally disrupts people's lives, ruins the economy, and has many kids kept

[1286] E-Mail from Francis Collins, Dir., National Institutes of Health, to Anthony Fauci, *et al*., Dir., National Institute for Allergy and Infectious Diseases (Oct. 8, 2020, 2:31 PM).
[1287] Joel Achenbach, *Proposal to hasten herd immunity to the coronavirus grabs White House attention but appalls top scientists*, THE WASH. POST (Oct. 14, 2020).
[1288] *Id.*
[1289] *See generally*, Matt Reynolds, *There is no 'scientific divide' over herd immunity*, WIRED (Oct. 7, 2020).
[1290] Zuckerberg Letter, *supra* note 1123.
[1291] Vinay Prasad & Jeffrey S. Flier, *Scientists who express different views on Covid-19 should be heard, not demonized*, STAT (Apr. 27, 2020).

> out of school in a way that they never quite recovered is a public-health mindset…another mistake we made.[1292]

At a March 8, 2023 Select Subcommittee hearing, Congressman Ronny Jackson (R-T.X.) asked Dr. Redfield what can be done to gain back to trust of public health officials.

> **Dr. Robert Redfield (March 8, 2023)**
>
> …The second thing, you have to have the courage when you're a public health official to say, I don't know, when you don't know. And I think the really fundamental—that's how we begin to lose it when people say that we're going to be OK once we get 30 percent immunity, and then later they say 50 percent, and then later they say 70 percent. And then the press says, well, why did you say 50 percent before, and now you're saying 70 percent? And the [public health officials] says, well, I didn't think the public was ready to hear that.[1293]

Public health leaders' aggressive exclusion of natural immunity even being considered to be a part of fighting the COVID-19 virus created an environment of hostility in the scientific community that will produce lasting adverse effects. Public health leadership appeared to only push a single agenda and not foster an atmosphere of mutual respect and robust discussion.

[1292] Braver Angels, *supra* note 858; *See also*, Scott Atlas, Steve Hanke, Philip Kerpen, & Casey Mulligan, *COVID Lessons Learned: A Retrospective After Four Years*, COMM. TO UNLEASH PROSPERITY (Mar. 2024).
[1293] Investigating the Origins of COVID-19, *supra* note 12.

V. Vaccine Mandates Were Not Supported by Science and Caused More Harm than Good

The FDA issued EUAs for the Pfizer-BioNTech and Moderna COVID-19 vaccines in December 2020.[1294] The EUA for the Janssen (Johnson and Johnson) COVID-19 vaccine was issued in February 2021.[1295] By early February, the U.S. had administered approximately 26.5 million vaccinations, one of the fastest rollouts in the world.[1296] By the late February, the doses administered had nearly doubled to 50 million doses administered.[1297]

On March 19, 2021, the U.S. administered its 100-millionth vaccine.[1298] By April 18, half of all U.S. adults had received at least one COVID-19 dose,[1299] and on April 19 all U.S. adults became eligible for a vaccine.[1300] In early August 2021, 70 percent of the U.S. population had been vaccinated, including 90 percent of Americans aged 65 and older.[1301]

In December 2020, President-Elect Biden stated he would not make vaccines mandatory. President Biden and other officials within the administration repeated this promise throughout much of early and mid-2021 as the vaccines were rolled out.[1302] However, the promise was soon broken when, on August 24, 2021, Secretary Austin announced the first federal COVID-19 vaccine mandate—one day after the FDA's full approval of the Pfizer vaccine. This first COVID-19 vaccine mandate required the secretaries of each Military Department to "immediately begin full vaccination of all members of the Armed Forces under DoD authority." Secretary Austin also noted that this decision was made "with the support of the President."[1303] DOD did not, however, mention or reference specific scientific studies supporting its mandate. Further, Secretary Austin has repeatedly ignored letters from members of Congress regarding making data-driven decisions concerning the health of the military.[1304]

After DOD issued its mandate, the floodgates of federal mandates opened. On September 9, 2021, President Biden issued Executive Order 14043, which required federal employees to be vaccinated against COVID-19 by November 8, 2021, or risk removal or termination from their federal employment.[1305] On November 4, 2021, OSHA issued a rule which required all

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[1294] *COVID-19 Vaccines*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, *available at* https://www.hhs.gov/coronavirus/covid-19-vaccines/index.html.
[1295] *Id*.
[1296] AJMC Staff, *A Timeline of COVID-19 Vaccine Developments in 2021*, AJMC (Jun. 3, 2021).
[1297] *Biden marks 50M vaccine doses in first 5 weeks in office*, ASSOCIATED PRESS (Feb. 25, 2021).
[1298] Zeke Miller, *Biden eyes new goal after US clears 100M shots since Jan. 20*, ASSOCIATED PRESS (Mar. 19, 2021).
[1299] Jeannette Muhammad, *Global COVID-19 Deaths Top 3 Million*, NATIONAL PUBLIC RADIO (Apr. 17, 2021).
[1300] *Biden marks 50M vaccine doses in first 5 weeks in office*, ASSOCIATED PRESS (Feb. 25, 2021).
[1301] AJMC Staff, *What We're Reading: 70% of US Vaccinated; CMS Payment Rules Released; Alcohol Consumption and Cancer*, AJMC (Aug. 3, 2021).
[1302] Tommy Pigott, *Biden Promised No Mandate. He Lied*, RAPID RESPONSE (Sept. 10, 2021).
[1303] Memorandum for Senior Pentagon Leadership Commanders of the Combatant Commands Defense Agency and DOD Field Activity Directors, *Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Member* (Aug. 24, 2021).
[1304] Press Release, Congressman Brad Wenstrup, *Wenstrup Demands Substantive Response from DOD After Receiving Four-Sentence Reply* (Feb. 27, 2023).
[1305] *Guidance on Enforcement of Coronavirus Disease 2019 Vaccination Requirements for Federal Employees – Executive Order 14043*, U.S. OFFICE OF PERSONNEL MANAGEMENT; *See,* Exec. Order No. 14043, 86 Fed. Reg. 50985 (Sept. 14, 2021).

employers with 100 or more employees to impose COVID-19 vaccine mandates, and CMS announced a COVID-19 vaccine mandate for all healthcare workers who worked at facilities participating in Medicare and Medicaid.[1306] Finally, on November 30, 2021, HHS announced a rule which required COVID-19 vaccination for all Head Start staff, contractors and volunteers.

Although all five of the major federal COVID-19 vaccine mandates are now rescinded, overturned, or otherwise ended, their consequences will live on for years to come. The COVID-19 vaccine mandates caused people to lose their livelihoods, hollowed out our healthcare and education workforces, reduced our military readiness and recruitment, caused vaccine hesitancy, reduced trust in public health, trampled individual freedoms, deepened political divisions, and interfered in the patient-physician relationship.

Aside from these severe consequences, the scientific basis of the COVID-19 vaccine mandates was highly questionable. COVID-19 mandates ignored natural immunity, stratification of risk from the virus, risk of adverse events from the vaccine, as well as the fact that the vaccines don't prevent the spread of COVID-19. Meanwhile, as the Select Subcommittee has established in previous hearings, federal health officials consistently overstated the power of the vaccines and deepening political divides with statements like "the pandemic of the unvaccinated."[1307] This is yet another example of the Biden Administration's guidance and policies straying far outside boundaries of the available evidence while proudly proclaiming they were "following the science."[1308] For them, "because I told you so" was good enough.

DOD Mandate

Secretary Austin issued the DOD COVID-19 vaccine mandate on August 24, 2021[1309], and it remained in effect until he rescinded it on January 10, 2023[1310], as required by the National Defense Authorization Act (NDAA) for FY2023.[1311] Over the course of the 16 months that the COVID-19 vaccine mandate was in effect, approximately 8,000 service members were separated due to their COVID-19 vaccination status.[1312] However, more than 17,500 troops' religious exemptions were still being adjudicated just prior to the rescission of the COVID-19 vaccine mandate.[1313] Some have also argued that the NDAA language did not go far enough to ameliorate the harms done by the COVID-19 vaccine mandate since separated servicemembers

[1306] Release, White House, *Fact Sheet: Biden Administration Announces Details of Two Major Vaccination Policies* (Nov. 4, 2021).
[1307] President Joe Biden, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sept. 9, 2021).
[1308] President Joe Biden, *Statement by President Joe Biden on CDC Guidance* (July 27, 2021).
[1309] Release, White House, *Fact Sheet: Biden Administration Announces Details of Two Major Vaccination Policies* (Nov. 4, 2021).
[1310] *DOD Rescinds COVID-19 Vaccination Mandate*, U.S. DEP'T OF DEFENSE (Jan. 10, 2023).
[1311] James M. Inhofe National Defense Authorization Act for Fiscal Year 2023, Pub. L. No. 117-263, Stat. 2395 (2022).
[1312] Oren Liebermann, *Only 43 of more than 8,000 discharged from US military for refusing Covid vaccine have rejoined*, CNN (Oct. 2, 2023).
[1313] Steve Beynon, *Thousands of Troops with COVID Vaccine Exemption Requests No Longer Facing Separation With Mandate Gone*, MILITARY TIMES (Jan. 4, 2023).

would not be automatically reinstated or paid back-pay.[1314] The Select Subcommittee agrees that members should be reinstated with back-pay.

Federal Workforce Mandate

On September 9, 2021, President Biden issued Executive Order 14043 which mandated all 3.5 million Federal employees get a COVID-19 vaccine by November 22, 2021.[1315] In the press release issued by the White House, President Biden stated that "[t]he health and safety of the Federal workforce, and the health and safety of members of the public with whom they interact, are foundational to the efficiency of the civil service" and that "[the COVID-19 vaccines] protect people from getting infected and severely ill, and they significantly reduce the likelihood of hospitalization and death." The Biden Administration formally ended this mandate (along with the CMS mandate) at the end of the public health emergency on May 11, 2023.[1316]

OSHA Mandate

On November 4, 2021, the Biden Administration announced that it would be using OSHA to require all businesses with more than 100 employees to impose COVID-19 vaccine mandates.[1317] Under this Emergency Temporary Standard [hereinafter "ETS"], employees would be required to be vaccinated or face weekly testing. Companies would also have to give workers paid time off to receive vaccines and to recover from any adverse effects. Companies that did not comply would face up to $14,000 in fines per violation.[1318]

This was met with immediate questions about whether OSHA had the authority to impose such a requirement. On November 9, 2021, the National Federation of Independent Businesses [hereinafter "NFIB"] filed a lawsuit against OSHA regarding this ETS.[1319] Shortly thereafter, on November 12, 2021, the Fifth Circuit Court of Appeals issued a stay.[1320] On December 17, 2021, the Sixth Circuit Court of Appeals vacated the Fifth Circuit Court's stay, which allowed the ETS to be implemented. On January 13, 2022, the Supreme Court sided with NFIB and blocked OSHA from enforcing the ETS only three days after it took effect. However, many employers had already implemented COVID-19 vaccine mandates by this point.

[1314] Press Release, Ted Cruz, U.S. Senator for Texas, Sen. Cruz Introduces Updated Legislation Building on Vaccine Mandate Ban to Reinstate Service Members Fired Over COVID Vaccine (Jan. 24, 2023).
[1315] President Joe Biden, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sept. 9, 2021).
[1316] Release, White House, The Biden-Harris Administration Will End COVID-19 Vaccination Requirements for Federal Employees, Contractors, International Travelers, Head Start Educators, and CMS-Certified Facilities (May 1, 2023).
[1317] Release, U.S. Dep't of Defense, *DOD Rescinds COVID-19 Vaccination Mandate* (Jan. 10, 2023).
[1318] Press Briefing by Mr. Munoz, *Background Press Call on OSHA and CMS Rules for Vaccination in the Workplace*, White House Briefing Room (Nov. 4, 2021).
[1319] *NFIB Files Lawsuit Against OSHA's Vaccine Mandate on America's Businesses* (Nov. 9, 2021).
[1320] *BST Holdings LLC, et al. v. OSHA, et al.* No. 21-60845 (5th Cir. 2021).

CMS Mandate

In the same November 4, 2021 announcement of the OSHA COVID-19 vaccine mandate, the Biden Administration simultaneously announced that it would be proceeding with a COVID-19 vaccine mandate for all health care workers who worked at facilities that participate in Medicare and Medicaid. Due to the incredibly large scale of these two federal programs, this mandate covered approximately 10 million people and around 76,000 healthcare providers.[1321] This was among the most consequential COVID-19 vaccine mandates due to the significant number of individuals within its scope, the fact that it remained in effect until May 2023, and because of the damage it did to the health care workforce in the middle of a pandemic. Many healthcare workers voluntarily quit or were fired for not complying with the mandate.[1322]

Head Start Mandate

On November 30, 2021, the Office of Head Start—the early education federal program within HHS—announced an interim final rule [hereinafter "IFR"] imposing both vaccination and masking requirements for grant recipients of the program.[1323] Specifically, the IFR mandated the COVID-19 vaccine for all staff, volunteers, and contractors, and universal masking for all individuals two years of age or older.[1324] Prior to May 11, 2023—the formal end of the COVID-19 public health emergency—the Biden Administration had been prohibited from enforcing the Head Start mandate by a federal district court judge on September 21, 2022.[1325]

Other Jurisdictions:

The Biden Administration's federal COVID-19 vaccine mandates directly imposed vaccination requirements on more than 12 million Americans, but even individuals not within the scope of these mandates were likely to come across another entity imposing one.[1326] Many of these entities may have even been encouraged to do so because of the federal COVID-19 vaccine mandates, even if not compelled to do so. States, counties, municipalities, schools, employers, restaurants, airlines, gyms, entertainment venues and many others across the country, imposed COVID-19 vaccine mandates.

In response to the OSHA mandate, many private companies pushed to implement their own vaccine policies. After the FDA hurriedly granted full approval for the Pfizer vaccine on August 23, 2021, these companies, amongst others, announced some form of vaccination plan: American Express, Amtrak, Cisco, Citigroup, CVS Health, Deloitte, Delta Airlines, DoorDash, Equinox, Facebook, Ford, General Electric, Goldman Sachs, Google, Lyft, McDonalds, MGM Resorts International, Microsoft, Morgan Stanley, NBCUniversal, Netflix, The New York Times, Saks, Southwest Airlines, Twitter, Uber, United Airlines, Walgreens, The Walt Disney

[1321] Tom Hals, *Judge blocks U.S. COVID-19 vaccine rule for health workers in 10 states*, REUTERS (Nov. 29, 2021).
[1322] Dave Muoio, *How many employees have hospitals lost to vaccine mandates? Here are the numbers so far*, FIERCE HEALTHCARE (Feb. 22, 2022).
[1323] 86 Fed. Reg. 68,052 (Nov. 30. 2021).
[1324] *Id*.
[1325] *Louisiana v. Becerra*, 3:21-CV-04370 (W.D. La. Sep. 21, 2022).
[1326] *See Where 12 Million U.S. Employees Are Affected by Government Vaccine Mandates*, THE N.Y. TIMES (Dec. 18, 2021).

Company, Walmart, and The Washington Post.[1327] Individuals who refused to comply with these COVID-19 vaccine mandates were fired from their jobs and many more people opted to quit instead.[1328]

College campuses across the country were another area significantly impacted by COVID-19 vaccine mandates. Prior to the COVID-19 vaccine rollout, college students had already been robbed of the traditional college experience and doors were opened in piecemeal and inconsistent ways. However, the implementation of COVID-19 vaccine mandates across campuses brought new disruptions. There were still many campuses in 2023 that required students to receive a COVID-19 vaccine and boosters, even though booster shots have been shown to be unnecessary for younger people[1329] and that the risk for myocarditis is higher in young men.[1330]

The negative effects brought by COVID-19 lockdowns has been widely reported, and for some, the so-called "vaccine passport" requirements became a new de-facto lockdown. For example, in Washington DC, bars, gyms, concert venues and other businesses were forced to require proof of COVID-19 vaccination for their patrons.[1331] Even after the COVID-19 vaccine mandate was dropped,[1332] many businesses elected to keep their vaccination requirement in effect.[1333] A similar story played out in other jurisdictions across the country.

FINDING:	COVID-19 Vaccine Mandates Caused Massive Collateral Damage and Were Very Likely Counterproductive.

Vaccines alone, and therefore COVID-19 vaccine mandates, could not and did not bring us to "herd immunity."[1334] Yet, they caused collateral damage that has been felt by millions of Americans.

A May 2022 *British Medical Journal* [hereinafter "BMJ"] *Global Health* paper written by Dr. Bardosh and several other public health and bioethics experts from around the world found that COVID-19 vaccine mandates caused significant collateral damage. The paper's summary stated:

[1327] Haley Messenger, *From McDonald's to Goldman Sachs, here are the companies mandating vaccines for all or some employees*, NBCNEWS (Aug. 3, 2021).
[1328] Andrea Hsu, *Thousands of Workers are Opting to Get Fired, Rather than take the Vaccine*, NATIONAL PUBLIC RADIO (Oct. 24, 2021).
[1329] Berkeley Lovelace Jr., *Younger, health people don't need another COVID booster, vaccine expert says*, NBCNEWS (Jan. 11, 2023).
[1330] Berkeley Lovelace, Jr., *Small study points to possible cause of myocarditis following mRNA vaccination in young men*, NBCNEWS (May 5, 2023).
[1331] Karina Elwood & Fritz Hahn, *Ready your vaccination cards: DC businesses prepare to enforce new mandate*, THE WASH. POST (Jan. 14, 2022).
[1332] Tori Bergel, *DC Is Ending Its Vaccination and Mask Mandates*, WASHINGTONIAN, (Feb. 14, 2022).
[1333] Tierney Plumb, *Some D.C. Restaurants and Bars Refuse to Stop Asking for Customers' Vax Status*, EATER (Feb. 16, 2022).
[1334] Christie Aschwanden, *Five reasons why COVID herd immunity is probably impossible*, NATURE (Mar. 18, 2021).

> Our analysis strongly suggests that mandatory COVID-19 vaccine policies have had damaging effects on public trust, vaccine confidence, political polarization, human rights, inequities and social wellbeing. We question the effectiveness and consequences of coercive vaccination policy in pandemic response and urge the public health community and policymakers to return to non-discriminatory, trust-based public health approaches.[1335]

The BMJ paper also found that COVID-19 vaccine mandates primarily served to encourage vaccination in younger people who were the least at-risk for serious COVID-19 illness, and that this further entrenched distrust and provoked reactance:

> Although studies suggest that current policies are likely to increase population-level vaccination rates to some degree, gains were largest in those under 30 years old (a very low-risk group) and in countries with below average uptake. Moreover, insights from behavioral psychology suggest that these policies are likely to entrench distrust and provoke *reactance*—a motivation to counter an unreasonable threat to one's freedom.[1336]

Dr. Bardosh testified before the Select Subcommittee during a July 27, 2023 hearing titled "Because I Said So: Examining the Science and Impact of COVID-19 Vaccine Mandates." Dr. Bardosh was able to further expand on these findings on COVID-19 vaccine mandates.

> **Dr. Kevin Bardosh (July 27, 2023)**
>
> Q. Dr. Bardosh, let's amplify some of the points from your publications. There was a collaborative effort that you published with researchers and physicians from Johns Hopkins, Harvard, and Oxford, yes or no?
>
> A. Yes.
>
> Q. Did the COVID vaccine mandates from your research, from your publication with others, erode civil liberties?
>
> A. Yes, it did.
>
> Q. Did the COVID vaccine mandates fracture trust in public health officials?
>
> A. Yes, it did.

[1335] Bardosh, The unintended consequences of COVID-19 vaccine policy, *supra* note 891.
[1336] *Id.*

Q. Did the COVID vaccine mandates create financial stress to individuals and families who lost their jobs to the COVID mandates?

A. Absolutely.

Q. And Dr. Bardosh, do you feel that the decrease in individuals receiving routine pediatric immunizations for their children, do you feel that is due to the mandates of the COVID vaccine?

A. Yes, I do.

Q. And, finally, and I thank you for your brevity. Dr. Bardosh, do you feel that the COVID–19 vaccine mandates have harmed America?

A. Yes, I do.[1337]

This collateral damage may have hampered our preparedness for a future pandemic. Dr. Bardosh testified that COVID-19 vaccine mandates decreased public confidence in vaccines and would likely be responsible for resistance to vaccines during a future pandemic.

Dr. Kevin Bardosh (July 27, 2023)

Q. Dr. Bardosh, your paper in the British Medical Journal of Global Health discusses the unintended consequences of the COVID-19 vaccine mandates. The Biden administration imposed several, including the DOD mandate for military service members, the executive order mandate for federal employees and contractors, the OSHA mandate for employers with 100 or more employees, the CMS mandate for health care workers at facilities that participate in Medicare and Medicaid, and the HHS Head Start Program COVID-19 vaccine mandate for which we know young children are at the least risk. Can you highlight the ramifications of these mandates, such as no jab, no jab policies, vaccine passports and social lockdowns for the unvaccinated?

A. There is no doubt in my mind that these mandate policies are going to be responsible for the increase in distrust the next time there's a pandemic and the mobilization of resistance to a future vaccine in a future pandemic. And I think it's really shocking, and kind of a little bit sad, that my colleagues in the public health community, who are pro-mandate, don't understand this.[1338]

[1337] Because I Said So: Examining the Science and Impact of COVID-19 Vaccine Mandates: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 1, (July 27, 2023) [hereinafter "Because I Said So"].
[1338] *Id.*

As Dr. Bardosh highlighted in the BMJ paper, vaccine mandates appear to have also deepened political divisions. Rhetoric from some politicians and public health officials painted the vaccine mandates as a necessary policy to combat the selfish, ignorant, or malevolent "unvaccinated" who were perpetuating the pandemic. Americans wanted to be honestly educated about both the virus and the vaccines, not indoctrinated. During the Select Subcommittee's July 27, 2021 hearing, Dr. Bardosh testified that this rhetoric was a "scapegoating response," which evidence indicates may be counterproductive as a public health strategy.

Dr. Kevin Bardosh (July 27, 2023)

Q. Dr. Bardosh, in your paper, you mentioned that political leaders singled out the unvaccinated and blamed them for the continuation of the pandemic. In fact, in July 2021, during the onset of the Delta variant wave, CDC Director Rochelle Walensky said that it was ''becoming a pandemic of the unvaccinated.'' Is this the sort of blame, Dr. Bardosh, that you were referring to in your paper?

A. Yes, it is a scapegoating response.

A. Dr. Bardosh, I am going to make this simpler. Do you believe that this sort of language is harmful when we look for public officials in charge to scapegoat?

A. I think, you know, the HIV/AIDS community has done a lot of research on stigma and scapegoating, right? And, you know, decades of research has shown that stigma as a public health strategy is counterproductive. I will leave it at that.[1339]

In a December 2022 interview with Fox 5 New York, Dr. Anthony Fauci appeared to admit this fact, saying "[I] would like people to use good judgment to protect themselves and their family in that community without necessarily having to mandate anything, because, you know, there is a fatigue about being mandated. People don't like to be told what to do."[1340] Yet, this was too-little too-late. Dr. Fauci himself had already made extremely inflammatory remarks about the unvaccinated, including during an interview for an audiobook by journalist Michael Specter, where he patronizingly deemed concerns about not getting vaccinated as simply "ideological bullshit," and implied that institutions should make life difficult for the unvaccinated using vaccine mandates:

Once people feel empowered and protected legally, you were going to have schools, universities, and colleges are going to say; "you want to come to this college, buddy? You're going to get vaccinated. Lady, you're going to get vaccinated." Big corporations like Amazon and Facebook and all of those others are going to say; "you want to work for us, you get vaccinated."

[1339] Vaccine mandates hearing transcript page 30

[1340] Julia Musto, *Fauci acknowledges Americans have mandate 'fatigue': 'People don't like to be told what to do'*, FOX NEWS (Dec. 10, 2022).

> And it's been proven that when you make it difficult for people in their lives, they lose their ideological bullshit, and they get vaccinated.[1341]

During the Select Subcommittee's June 3, 2024 hearing, Dr. Fauci did acknowledge in hindsight that not all objections to COVID-19 vaccines were ideological bullshit.

> **Dr. Anthony Fauci (June 3, 2024)**
>
> Q. Are all objections to COVID vaccinations ideological bullshit, Dr. Fauci?
>
> A. No, they're not.[1342]

Some also argued that COVID-19 vaccine mandates would be self-defeating to their stated goal of ending the pandemic. In June 2021, Psychologist Katrin Schmelz and Economist Samuel Bowles co-wrote a *Washington Post* article titled; "Imposing vaccine mandates may be counterproductive, our research suggests."[1343] Schmelz and Bowles wrote that their research suggested it could "hurt voluntary compliance, prolonging the pandemic and raising its social costs."[1344] Specifically, their representative panel survey in Germany showed that:

> [M]aking vaccination a legal requirement might have retarded the rate of vaccinations, as it would have substantially reduced willingness to be vaccinated, consistent with self-determination and reactance theory in psychology and what economists' term "control aversion.[1345]

Vaccine mandates appear to have also contributed to a surge in vaccine hesitancy and overall distrust of public health authorities. For example, a recent CDC study showed that immunization rates for kindergarteners fell each year since the start of the pandemic.[1346] This trend could prove to be problematic for vaccination efforts during a future pandemic.

COVID-19 vaccine mandates also forced millions of people to choose between their livelihoods and being vaccinated—even if they had closely held personal or religious beliefs or a medical reason. This is not only unjust, but it also caused thousands of people to lose their jobs in the middle of a pandemic and unstable economic environment.[1347]

During the Select Subcommittee's July 27, 2023 hearing, Ms. Allison Williams testified about losing her job as an ESPN sports reporter after she sought an exemption to Disney's

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[1341] Michael Specter, Fauci (Puskin 2020) (audio).
[1342] Fauci Hearing, *supra* note 231, at 97
[1343] Katrin Schmelz & Samuel Bowles, *Imposing vaccine mandates may be counterproductive, our research suggests,* THE WASH. POST (June 7, 2021).
[1344] *Id.*
[1345] *Id.*
[1346] Ranee Seither, *et al., Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2023–24 School Year*, MMWR (Oct. 17, 2024).
[1347] *Id.*

COVID-19 vaccine mandates. Ms. Williams told the Select Subcommittee that at the time of the mandate she was actively working with fertility specialists while she and her husband were trying for their second child.[1348] Her doctor supported her decision to forgo the vaccine due to her young age, good health, and ongoing efforts to conceive a child.[1349] Nonetheless, Ms. Williams employment was terminated.[1350]

> **Ms. Allison Williams (July 27, 2023)**
>
> Just like that, newly pregnant, I was stripped of my job, my health insurance and having my personal and medical decisions the topic of national news. It is hard to explain what it is like to have so much taken from you for doing what you know in your heart and mind to be the right thing for you and your family. The financial toll it took on my family and so many others like us was significant, and still enduring. The lost wages and sacrifices made by families like mine who stood up to the overreaching, unjustified mandates to preserve their autonomy and health can never be fully recovered.[1351]

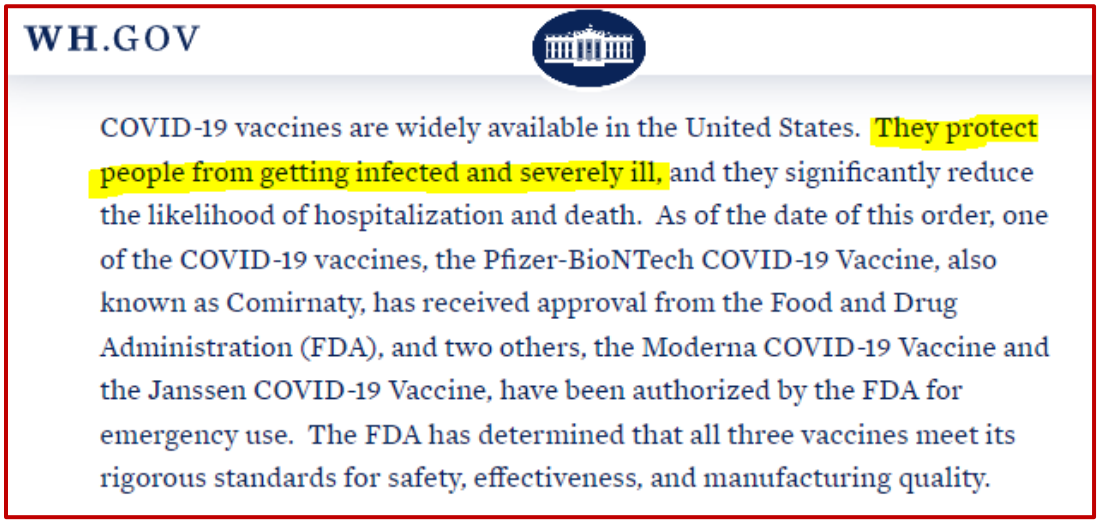
Worse still, one of the most impacted sectors, due to the CMS COVID-19 vaccine mandate, was our healthcare work force. The very same people heralded as "heroes" in 2020 were soon being fired for noncompliance in 2021.[1352] This notion is absurd on its face, but it is taken to another level given the fact that the healthcare workforce, particularly in the nursing field, was at crisis-level shortages across the country during this time.

In a December 2022 article, the AP highlighted this absurd hypocrisy and noted that "foundations are pouring millions of dollars into efforts to ensure that more stay in the [nursing] profession."[1353] The AP also cited an April 2022 study published by *Health Affairs* which showed that more than 100,000 nurses, or 1.8 percent of the nationwide work force, left in 2021.[1354] Many of these potential consequences were known prior to the federal COVID-19 vaccine mandates and were being widely discussed throughout the media, yet the Biden Administration continued anyway.[1355] Sadly, many of the individuals who were fired or left their jobs likely acquired natural immunity from previous infection and this immunity may have been greater than immunity acquired through vaccination.

[1348] Because I Said So: Examining the Science and Impact of COVID-19 Vaccine Mandates: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 1, (July 27, 2023) [hereinafter "Because I Said So"].
[1349] *Id.*
[1350] *Id.* at 30.
[1351] *Id.*
[1352] Dave Muoio, *How many employees have hospitals lost to vaccine mandates? Here are the numbers so far,* FIERCE HEALTHCARE (Feb. 22, 2022); Honoring Our Public Heroes Who Protect Us All, CDC Foundation, *available at* https://www.cdcfoundation.org/hero#:~:text=A%20hero%20is%20every%20public,essential%20health%20and%20wellbeing%20services.
[1353] Alex Daniels, *Foundations, major donors tackle nation's nursing shortage*, ASSOCIATE PRESS (Dec. 5, 2022).
[1354] David I. Auerbach, *et al., A Worrisome Drop In The Numbers Of Young Nurses*, HEALTH AFFAIRS FOREFRONT (Apr. 13, 2022).
[1355] Taylor Dotson & Nicholas Tampio, *Vaccine mandates will backfire. People will resist even more*, THE WASH. POST (July 31, 2021).

FINDING: COVID-19 Vaccine Mandates Were Not Supported by Science.

Not only did COVID-19 vaccine mandates cause many unintended consequences, but they were also not based in science. In President Biden's September 9, 2021, announcement of the federal workforce mandate, he cited the notion that the vaccines protect against infection as the first example for why the mandate was necessary.[1356]



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COVID-19 vaccines are widely available in the United States. They protect people from getting infected and severely ill, and they significantly reduce the likelihood of hospitalization and death. As of the date of this order, one of the COVID-19 vaccines, the Pfizer-BioNTech COVID-19 Vaccine, also known as Comirnaty, has received approval from the Food and Drug Administration (FDA), and two others, the Moderna COVID-19 Vaccine and the Janssen COVID-19 Vaccine, have been authorized by the FDA for emergency use. The FDA has determined that all three vaccines meet its rigorous standards for safety, effectiveness, and manufacturing quality.

However, it was already evident then and is now commonly known that the vaccines do not prevent you from getting infected or transmitting the virus.[1357] This seems to invalidate the most basic logic of a vaccine mandate. As noted by Dr. Vinay Prasad, Professor in the Department of Epidemiology and Biostatistics at the University of California San Francisco, "medical mandates are impermissible if they do not provide benefit to third parties."[1358]

The COVID-19 vaccine mandates also largely ignored the notion of naturally acquired immunity. By the standard of most COVID-19 vaccine mandates, there was no exception made for those who had previously contracted the virus. Rather, the more common exception was to allow weekly testing in place of being fully vaccinated. Chairman Wenstrup has direct experience with the disregard for natural immunity acquired from previous infection. The Chairman was vaccinated with the two-shot Pfizer vaccine. Six months later, he got COVID with mild symptoms.[1359] A House healthcare provider told the Chairman he needed a booster shot prior to going on official travel.[1360] Concerned about a hyperimmune response because of his recent recovery from infection, the Chairman asked for his antibody numbers—a strong number is 40, but the Chairman's number was 821.[1361]

[1356] President Joe Biden, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sept. 9, 2021).
[1357] Umair Irfan, *Some Vaccinated People Have Gotten COVID-19, That's No Reason to Panic*, VOX, (July 15, 2021).
[1358] Vinay Prasad (@VPrasadMDMPH), Twitter, (May 13, 2023, 1:46 PM) *available at* https://twitter.com/VPrasadMDMPH/status/1657442159904038913.
[1359] Because I Said So, *supra* note 1348, at 42.
[1360] *Id.*
[1361] *Id.*

This appears to fly in the face of decades of scientific research. While COVID-19 was a novel virus, there was clear science that infections from coronaviruses, including SARS-CoV-1, produced natural immunity.[1362] In 2021, once research began to emerge specifically about SARS-CoV-2, this notion was further supported. A study published in October 2021, using data from Italy, showed that re-infections were rare, and that protection lasted around one year.[1363] Further studies concurred with this, and some even directly questioned the logic of COVID-19 vaccine mandates.[1364]

In February 2023, a study was published in *The Lancet* that showed that natural immunity provides the same protection as two doses of an mRNA vaccine.[1365] Specifically, it showed that infection-acquired immunity cut the risk of hospitalization and death by 88 percent for at least 10 months.[1366] This study was the first to "comprehensively assess natural immunity protection against COVID-19 reinfection by variant (primary infection and reinfection) and to evaluate waning immunity with time since primary infection."[1367]

Relatedly, the COVID-19 vaccine mandates applied a one-size-fits-all approach to medicine which seriously undermined the patient-physician relationship. The mandates decreased the doctor's decision-space to make individualized risk-based assessments to determine the proper course of action. This meant that regardless of previous infection from COVID-19, previous adverse reactions to vaccines, likelihood to suffer an adverse effect from the COVID-19 vaccine, or risk of serious illness from COVID-19 – all individuals were seen the same by COVID-19 vaccine mandates.

FINDING: COVID-19 Vaccine Mandates Hampered U.S. Military Readiness.

According to reports, only 43 of the more than 8,000 separated servicemembers rejoined the military.[1368] The DOD COVID-19 vaccine mandate directly led to the separation of thousands of US servicemembers, but it has also hindered the military's ability to recruit. In fiscal year 2022, the military missed its recruiting goal by 15,000 personnel—25 percent of its target.[1369]

[1362] Li-Ping Wu, *et al. Duration of Antibody Responses After Severe Acute Respiratory Syndrome* PUBMED CENTRAL (Oct. 13, 2007).
[1363] Jose Vitale, *et al. Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy*, PUBMED CENTRAL (May 28, 2021).
[1364] Sheena Meredith, *COVID-19: Why Are We Ignoring Infection-Acquired Immunity?*, MEDSCAPE (Feb. 28, 2022).
[1365] Akshay Syal, *Immunity acquired from a COVID infection is as protective as vaccination against severe illness and death, study finds*, NBCNEWS (Feb. 16, 2023).
[1366] Caroline Stein, *et al., Past SARS-CoV-2 infection protection against re-infection: a systematic review and meta-analysis*, THE LANCET (Mar. 11, 2023).
[1367] Steven Lim, *et al. Past SARS-CoV-2 Infection Protection Against Re-Infection: A Systematic Review and Meta-Analysis*, THE LANCET (Feb. 16, 2023).
[1368] SEE OREN IBERMAN CNN ARTICLE
[1369] David Barno & Nora Bensahel, *Addressing the U.S. Military Recruiting Crisis,* WAR ON THE ROCKS (Mar. 10, 2023).

While it is true that the recruiting shortfalls are likely also driven by other factors such as the increasing ineligibility of young people, low unemployment, and decreasing confidence in the military, there is little question that the COVID-19 vaccine mandate added to this problem. Plus, these other factors have also been exacerbated by our response to COVID-19 inside and outside of the military. For example, lockdowns and school closures certainly did little to help with the crisis of military eligibility in young people.[1370]

Some military leaders have agreed that the COVID-19 vaccine mandate negatively impacted recruitment and military readiness. In August 2022, Major General James O. Eifert of the Florida National Guard penned an op-ed in the Wall Street Journal titled *The Vaccine Mandate Puts National Security at Risk*. Maj. Gen. Eifert wrote:

> I've never been more worried about the future of the U.S. armed forces than I am right now. I say that as a concerned citizen who has served for more than 40 years, the last three of which have been as the adjutant general of the Florida National Guard. One of the military's most foundational duties is to recruit and retain men and women willing to defend their country. Unfortunately, current federal policy is rendering that goal unattainable.[1371]

Eifert goes on to argue that COVID-19 itself had not hurt his units' readiness, but rather the military's policy responses had. He also said he agreed with mandating the vaccine in the military at first but that "the circumstances have changed" and that the vaccines efficacy "appears to be shorter-lived than once thought."[1372]

Similarly, in December 2022 during the Reagan Foundation Defense Forum, the now former Marine Corps Commandant Gen. David Berger conceded that the COVID-19 vaccine mandate was "for sure" hurting military recruitment efforts.[1373]

Overall, it is highly concerning that the DOD elected to issue this controversial and sweeping mandate at a time when it was falling well short of recruiting goals. Also concerning is the questionable necessity of mandating the vaccine for such a young and healthy cohort of individuals who simultaneously faced higher risk of adverse events from the vaccine.[1374] Our nation's adversaries stood back and watched as we weakened our own military readiness due to this misguided policy.

[1370] Dave Philipps, *With Few Able and Fewer Willing, U.S. Military Can't Find Recruits*, THE N.Y. TIMES, (July 14, 2022).
[1371] James O. Eifert, *The Vaccine Mandate Puts National Security at Risk*, THE WALL ST. JOURNAL (Aug. 4, 2022).
[1372] *Id.*
[1373] Michelle Lee, *Top Marine general says COVID vaccine mandate is hurting military recruiting efforts*, FOX NEWS, (Dec. 5, 2022).
[1374] *Id.*

VI. The COVID-19 Vaccine, While Largely Safe and Effective, Had Adverse Events That Must be Throughoughly Investigated

According to the WHO, pharmacovigilance consists of "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem."[1375] Federal health agencies participate in a variety of interwoven pharmacovigilance efforts, including both passive and active surveillance.

Passive surveillance is the collection of unsolicited reports of adverse events that are sent to a centralized database.[1376] The Federal Government's preeminent passive surveillance system is the VAERS.[1377]

Active surveillance involves proactively gathering and analyzing data to verify signals found via passive surveillance, or to detect new ones.[1378] The Federal Government's primary avenues for active surveillance are FDA CBER Sentinel BEST System, CMS data, and CDC's VSD and V-Safe systems.[1379]

The COVID-19 pandemic exposed some potential shortcomings and issues with these systems. For example, in mid-2021, concerns arose that CDC and FDA were not able to successfully utilize their surveillance systems to quickly identify increased risk of myocarditis in young males receiving the Pfizer COVID-19 vaccine, that other countries, including Israel and France, were able to recognize.[1380] Specifically, on May 17, 2021, CDC reported that "rates of myocarditis reports in the window following COVID-19 vaccination have not differed from expected baseline rates."[1381] One week later, and in the wake of reports from Israel's Ministry of Health, CDC reversed their stance by saying the rates were "higher than expected."[1382]

FINDING: The Vaccine Adverse Event Reporting System is Insufficient and Not Transparent.

HHS describes VAERS as "a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the CDC and the FDA." [1383] VAERS is operated as a publicly available database which contains millions of reports which have been submitted by individuals. Importantly, healthcare professionals and vaccine manufacturers are specifically *required* to report adverse events that occur after a vaccination to VAERS, but anyone can report an adverse event.

[1375] *Regulation and Prequalification: What is Pharmacovigilance?,* WORLD HEALTH ORG.
[1376] *COVID-19 Vaccine Safety Surveillance,* U.S. FOOD & DRUG ADMIN. (Dec. 7, 2021).
[1377] U.S. Dept. of Health and Human Services, *Vaccine Adverse Event Reporting System (VAERS.),* U.S. DEP'T OF HEALTH & HUMAN SERVICES *(last visited Nov. 14, 2024).*
[1378] *CDC: Advisory Committee on Immunization Practices, COVID-19 VaST Work Group Report* (May 17, 2021).
[1379] *Id.*
[1380] *Id.*
[1381] *Id.*
[1382] Elizabeth Cohen, *A link between COVID-19 vaccination and a cardiac illness may be getting clearer,* CNN (Jun. 10, 2021).
[1383] *About VAERS,* U.S. DEP'T OF HEALTH & HUMAN SERVICES *available at* https://vaers.hhs.gov/about.html.

Although the system has been operational since 1990, it first became a source of significant controversy with the rollout of COVID-19 vaccines beginning in late 2020 and early 2021. During this time, many posts circulated on social media calling attention to alarming numbers of deaths and adverse events associated with COVID-19 vaccines.[1384] These posts were soon met with a barrage of fact-check articles refuting them.[1385]The chart below presents data from VAERS as of November 2024.[1386]

Worldwide VAERS Reports for COVID-19 Vaccines as of 11/30/2024[1387]	
Total Adverse Events	1,844,839
Hospitalizations	216,646
Permanent Disabilities	72,161
Deaths	38,068
Deaths Within Two Days of Vaccination	9,167

Possibly the most alarming figures are the comparisons between COVID-19 vaccines, which have only been widely available since early 2021, and all other vaccines combined since 1990. The charts below illustrate this comparison. [1388]

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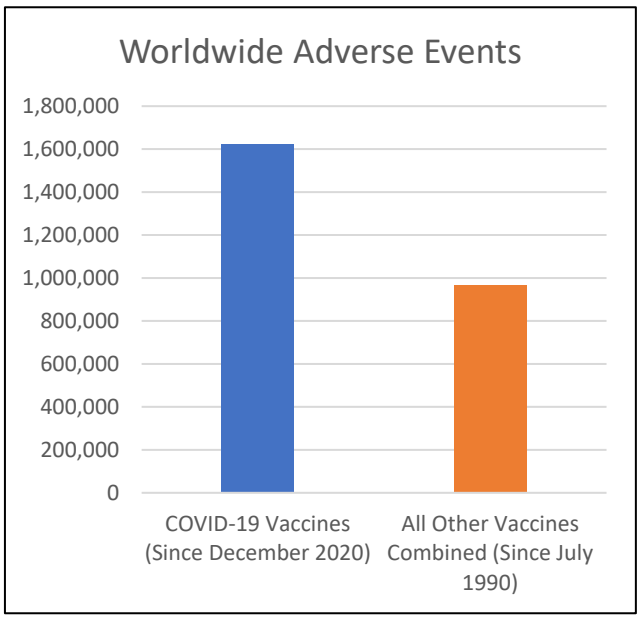
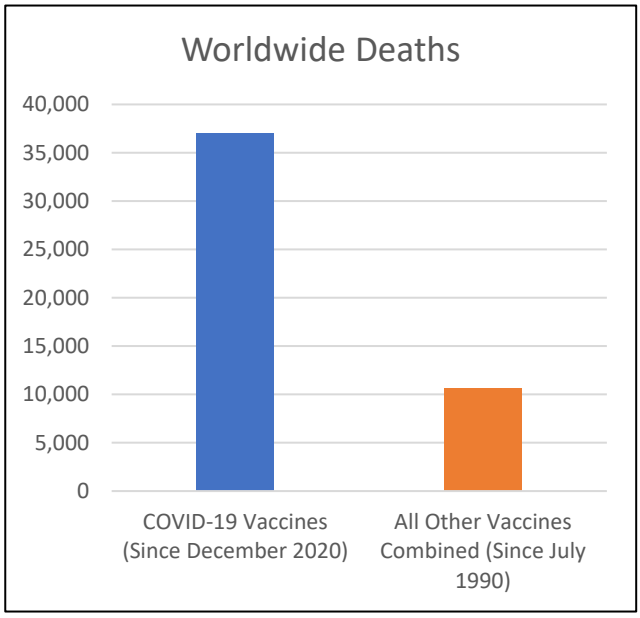
[1384] *See generally*, *Posts continue to misrepresent VAERS COVID-19 vaccine data*, ASSOCIATED PRESS (Sept. 23, 2022); Reuters Fact Check, *VAERS data does not suggest COVID-19 vaccines killed 150,000 people, as analysis claims*, REUTERS (Oct. 4, 2021); Catalina Jaramillo, *Viral Posts Misuse VAERS Data to Make False Claims About COVID-19 Vaccines*, FACTCHECK.ORG (Mar. 31, 2021).
[1385] *See generally, Posts continue to misrepresent VAERS COVID-19 vaccine data,* ASSOCIATED PRESS (Sept. 23, 2022); Reuters Fact Check, *VAERS data does not suggest COVID-19 vaccines killed 150,000 people, as analysis claims*, REUTERS (Oct. 4, 2021); Catalina Jaramillo, *Viral Posts Misuse VAERS Data to Make False Claims About COVID-19 Vaccines*, FACTCHECK.ORG (Mar. 31, 2021).
[1386] CDC WONDER On-line Database *available at* http://wonder.cdc.gov/vaers.html (last visited Nov 30, 2024).
[1387] *Id*.
[1388] *Id.*





As previously noted, anyone can submit a report to VAERS, and these reports are automatically published and available publicly. Therefore, a report on VAERS has likely not been proven to be caused by a vaccine. However, the vast discrepancy when comparing COVID-19 vaccines over three years, with all other vaccines over more than 30 years raises serious concerns. Pursuant to the EUA for COVID-19 vaccines, manufacturers and providers were required to report serious adverse events to VAERS irrespective of proof of attribution.[1389]

An investigation conducted by the BMJ raised concerns that VAERS "isn't operating as intended and that signals are being missed."[1390] The BMJ found several troubling issues, including that the system may be severely understaffed in the face of unprecedented number of new reports being filed in the wake of the massive campaign to administer COVID-19 vaccines.[1391]

Specifically, the BMJ reports that "VAERS's staffing was likely not commensurate with the demands of reviewing the serious reports submitted, including reports of death," and that "Pfizer has around 1,000 more full time employees working on vaccine surveillance than the CDC."[1392] The Journal highlighted that other countries have acknowledged deaths that were "likely" or "probably" caused by COVID-19 vaccines, but CDC has only acknowledged deaths "causally" caused by COVID-19 vaccines—which may be sign that the system is severely overwhelmed.[1393]

[1389] 86 Fed. Reg. 54111 (Jan. 19, 2021),
[1390] Jennifer Block, *Is the US's Vaccine Adverse Event Reporting System broken*? BMJ (Nov. 10, 2023).
[1391] *Id.*
[1392] *Id.*
[1393] *Id.*

The BMJ also found that VAERS representatives were inconsistent at following up on reports made to the system.[1394] The BMJ spoke to more than 12 people who filed serious reports to VAERS and were "never contacted or were contacted months later."[1395] This is made even worse since, as BMJ reported, the public database only contains preliminary reports, and all updates and corrections are housed on a "separate, back-end system" which is unavailable to patients, doctors, and other public users of the database.[1396]

The BMJ spoke with was Dr. Whelan. Dr. Whelan testified at a Select Subcommittee Hearing on March 21, 2024, where he explained that VAERS fails to cultivate trust.

Dr. Patrick Whelan (March 21, 2024)

Q. Dr. Whelan, do you believe that it is appropriate to house all of the potential updates and corrections to VAERS on a non-public data base?

A. I think that there is a lot of trust involved in the medical community, but also for the general public, that something is happening behind the scenes when you can't see it right out in front. And I think, two, that people were very aware that you did not have the kind of follow up on vaccination generally that we expect, for instance, from our pediatricians, where you got a nurse who is going to call the following week and make sure that your child is doing OK. And, I mean, my own strong feeling is that we really needed a much more proactive surveillance mechanism, and I think that many of us understand that the FDA was under enormous pressure and also that it was an overwhelming task. And just judging by the number of VAERS reports that there have been and knowing how challenging it can be to actually file a VAERS report, the task could have been even vastly larger than the large task that it already is. I mean, you have to have some level, I think, of internal dialog that takes place. But I think ultimately, as you alluded earlier, you have to be able to create some level of trust among people, and I think the system currently does not cultivate that.[1397]

During an interview about VAERS, vaccine expert and member of the CDC's ACIP, Dr. Paul Offit, told a story of a colleague who, to prove a point, successfully submitted a VAERS report saying that "he got a vaccine and he turned into the Incredible Hulk."[1398] Surprisingly, Director Walensky testified before the Select Subcommittee in June 2023 and said, "we at CDC have a responsibility to comb through every single one of them [VAERS reports] to review the

[1394] *Id.*
[1395] *Id.*
[1396] *Id.*
[1397] Assessing America's Vaccine Safety Systems Part II: Hearing Before Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 2 (Mar. 21, 2024).
[1398] MicrobeTV, *Beyond the Noise #26: VAERS,* YouTube (Jan. 16, 2024).

medical charts and to see if they are related."[1399] Per the BMJ investigation, it appears that these updates and corrections may not be reflected in the public version of VAERS.

All this controversy raises questions about whether VAERS is a sufficient or effective surveillance system as currently operated.

FINDING:	Existing Vaccine Safety Systems May Be Missing Important Safety Signals, Especially Related to Neurological Conditions.

In May 2024, *The New York Times* published an article which discussed the issue of COVID-19 vaccine injuries and the fact that many of those who have experienced one feel they have been ignored.[1400] The article focused on neurological issues that people believed were caused by the COVID-19 vaccine but have limited scientific evidence. For example, the article contained stories of individuals who had tinnitus after receiving a COVID-19 vaccine, including the Editor-in-Chief of the journal Vaccine, and a doctor who led several COVID-19 vaccine trials at Vanderbilt University.[1401]

Further, in the article Dr. Woodcock, expressed regret about the way that the FDA handled vaccine injuries during the pandemic.

> I believe their suffering should be acknowledged, that they have real problems, and they should be taken seriously.
>
> ***
>
> I'm disappointed in myself. I did a lot of things I feel very good about, but this is one of the few things I feel I just didn't bring it home.[1402]

Dr. Woodcock explained that she believes these neurological symptoms are difficult to establish causality for because they don't have well-defined research definitions.

> I mean, you're not going to find 'brain fog' in the medical record or claims data.[1403]

During her transcribed interview with the Select Subcommittee, Dr. Woodcock expanded on her statements to *The New York Times*. Dr. Woodcock testified that this difficulty with finding causality for neurological conditions existed before the COVID-19 pandemic because it is difficult to neatly put neurological symptoms into any diagnostic category.

[1399] Oversight of CDC Policies and Decisions During the COVID-19 Pandemic: *supra* note 1139 (statement of Dr. Rochelle Walensky, Dir., U.S. Ctrs. for Disease Control and Prevention).
[1400] Apoorva Mandavilli, *Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?,* THE N.Y. TIMES (May 3, 2024, updated May 4, 2024).
[1401] *Id.*
[1402] *Id.*
[1403] *Id.*

Dr. Janet Woodcock (May 13, 2024)

Q. The article indicates that you believe that some recipients of COVID vaccines "experienced uncommon but 'serious' and 'life changing' reactions beyond those described by federal agencies." What kinds of reactions are you referring to there?

A. I'm referring to reactions that medical science has trouble dealing with. A common problem that occurred before this, before COVID used to be called chronic fatigue syndrome or myalgic encephalitis. And the medical establishment has struggled for 20 years trying to figure out what it is and still have no idea. All right. That's typically a post viral or post infectious illness. However, I think it could occur post any immune stimulus. So to answer your question, folks had brain fog, fatigue, prostration, some of them had neurologic symptoms. None of them fit neatly into any diagnostic category.

Q. So because they didn't fit neatly inside a diagnostic category, you're saying they're harder to be described or analyzed?

A. Well, they're harder to be identified because many of these folk struggled for months and months to even be acknowledged that there was anything wrong with them. Many of them were told, you know, they were just – It's all in your head. And that's very similar to chronic fatigue syndrome, myalgic encephalitis.[1404]

Dr. Woodcock also testified that while Acting FDA Commissioner she had pushed for the NIH to establish a research arm to study these neuropathies' possible association with COVID-19 vaccines, so that the people experiencing them could get acknowledged and also to start exploring possible treatments.

Dr. Janet Woodcock (May 13, 2024)

A. I even talked to NIH, I talked to even see if they would add an arm, because this is very similar to some of the things that people get with long COVID. You get-- people get long COVID much more frequently after getting COVID than they do getting this after vaccination. But it does seem to happen. So I wanted to get it studied because I think what the first thing we need is study. And the NIH study on long COVID is looking for syndromic definitions. That's mainly what they're doing, they're trying to find syndromic clusters so they can name these conditions in some the same way that people get POTS, postural orthostatic tachycardic syndrome, which is another probably autonomic neuropathy, okay? So my goal

[1404] Woodcock TI, *supra* note 1171, at 110.

was to try and, number one, get the people studied so they can be acknowledged, that they were having a problem, and also start working up ideas of treatment. Now, I wasn't really that hopeful because CFS ME has gone so long without effective interventions.[1405]

Dr. Woodcock explained that these efforts ultimately stalled, apparently due to a lack of funding.[1406] However, she also indicated that she believed others at the FDA did not appear to have taken this issue as seriously as her.

Dr. Janet Woodcock (May 13, 2024)

Q. Why do you think that that stalled?

A. Well, I had too many things to do. And I think the main reason is without a signal, you know, like we get a lot of signals in our real, like I was telling you earlier. You have to work them up and they aren't causally related. That requires some strong causality – potentially causally related signals hardly get the companies to pay for it. They would have had to pay for a study like that at NIH.

Q. So do you feel that others within FDA took this as seriously as you did?

A. No.[1407]

It therefore appears that the government must do more to prioritize research into these conditions for the sake of those experiencing them, but also to preserve public trust in vaccination going forward.

FINDING: The U.S. Centers for Disease Control and Prevention Created a New Surveillance System Specifically for COVID-19 but has not been Fully Transparent in Sharing the Data Collected in it.

Launched in December 2020, V-Safe is an active surveillance system which specifically monitors the safety of COVID-19 vaccines.[1408] It prompts enrollees for health check-ins via text messages and web surveys whereby individuals report on post-vaccination experiences.[1409]

[1405] Woodcock TI, *supra* note 1171, at 112.
[1406] Woodcock TI, *supra* note 1171, at 114-115
[1407] Woodcock TI, *supra* note 1171, at 115.
[1408] *V-safe Landing Page,* U.S. CTRS. FOR DISEASE AND CONTROL, *available at* https://vsafe.cdc.gov/vsafeportal/s/login/?language=en_US&ec=302&startURL=%2Fvsafeportal%2Fs%2F.
[1409] *What is V-safe,?* U.S. CTRS. FOR DISEASE AND CONTROL; Tanya R. Myers, *et al., The v-safe after vaccination health checker: Active vaccine safety monitoring during CDC's COVID-19 pandemic response,* VACCINE (Jan. 23, 2023).

According to CDC, 10.1 million V-Safe participants completed more than 151 million surveys about their health experiences after receiving COVID-19 and mpox vaccines.[1410]

V-Safe is subject to a substantial amount of litigation. Specifically, CDC is defending against FOIA lawsuits filed by groups seeking data and millions of free-text responses gathered through the program.[1411] ICAN obtained and released the "checkbox" data in October 2022.[1412] ICAN also created a public dashboard which highlights the data, which they say contains "numerous alarming results."[1413] Specifically, ICAN reports that the data show 782,913 individuals, or more than 7.7 percent of users, reported a health event requiring medical attention, emergency room intervention, and/or hospitalization.[1414]

CDC is resistant to providing the free-text entries and have cited concerns that their release would be too burdensome, but a January 2024 court decision required the CDC release them over the course of the next 12 months.[1415] The plaintiffs claim the CDC "design[ed] V-Safe to assure harms are hidden in free-text fields," and that analysis of this data will allow "the rate of and adverse reaction [to] be calculated" which is "not possible with VAERS."[1416] If a system like V-Safe would be better equipped to actually calculate the rate of a particular adverse event, it is concerning that public health agencies have not leveraged this approach fully.

[1410] *About V-safe,?* U.S. CTRS. FOR DISEASE AND CONTROL
[1411] Jenna Greene, *New data is out on COVID vaccine injury claims. What's to make of it?* REUTERS (Oct. 12, 2022).
[1412] Press Release, Informed Consent Action Network, Breaking News: ICAN Obtains CDC V-safe Data (Oct. 3, 2022).
[1413] *Id.*
[1414] *Id.*
[1415] *Freedom Coalition of Doctors for Choice v. Centers for Disease Control and Prevention,* 2:23-cv-00102-Z, (N.D. Tex. Jan. 5, 2024); Greg Piper, *Judge orders CDC to quickly turn over millions of COVID vaccine-injury reports by early patients*, JUST THE NEWS (Jan. 13, 2024).
[1416] Aaron Siri, *V-Safe Part 4: CDC Designs V-Safe to Assure Harms Are Hidden in Free-Text Fields So It Can Control What Becomes Public, Including Limiting the Harms Submitted to VAERS*, INJECTING FREEDOM (Jan. 10, 2023).

VII. The U.S. Government's Insufficient Systems for Compensating COVID-19 Vaccine Injuries

Generally, vaccines are safe and effective. However, it is inevitable that some individuals will experience adverse events, sometimes serious, life-altering, or life-threatening. This is true for practically any pharmaceutical product and COVID-19 vaccines are no exception. Since vaccines are an important tool to protect public health, it is imperative to preserve the public's trust in vaccination, and therefore compensating for these rare but inevitable harms is of vital importance. Conversely, limiting the liability of manufacturers also promotes the expeditious development of new and innovative vaccine technology which saves lives.

Furthermore, the modern American legal system has long provided tools for proper compensation for injuries of all types. While this type of litigation is often misunderstood and sometimes abused, the system provides a crucial tool for people who have suffered harm to be made whole financially, emotionally, and otherwise. Vaccine injuries are no exception, and therefore modern societies have an obligation to ensure that there are proper systems in place to provide accountability, justice, and financial support for those who experience an injury attributable to a vaccination.

In pursuit of these goals, Congress created the VICP as part of the National Childhood Vaccine Injury Act of 1986.[1417] VICP covers all vaccines which are recommended for routine administration to children and/or pregnant women by the CDC.[1418] This list currently consists of 16 individual vaccines.[1419] VICP allows individuals to file a petition for compensation, and these petitions are then adjudicated by the Office of Special Masters [hereinafter "OSM"] which falls within the U.S. Court of Federal Claims.[1420] Awards are paid out from the Vaccine Injury Compensation Trust Fund which gets its funding from a $0.75 excise tax on each covered vaccine dose.[1421]

In 2005, Congress passed the PREP Act which contains provisions designed to promote the rapid development of vaccines in the case of a public health emergency, including the CICP.[1422] The CICP has a more limited scope than the VICP and provides compensation only for "covered countermeasures," including vaccines.[1423] Because the COVID-19 vaccines were purchased and distributed by the federal government under PREP Act authority, any serious injuries caused by them are compensated via CICP rather than VICP. The PREP Act also limits

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[1417] 42 U.S.C. § 300aa-10, et seq.
[1418] Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP), HEALTH RESOURCES & SERVICES ADMIN., *available at* https://www.hrsa.gov/cicp/cicp-vicp.
[1419] *Id.*
[1420] Hannah-Alise Rogers, CONG. RESEARCH SERVS., IF 12213, *The National Vaccine Injury Compensation Program and the Office of Special Masters* (Sept. 14, 2022).
[1421] *Id.*
[1422] 42 U.S.C. § 247-6d(a)–(b).
[1423] *Countermeasure Injury Compensation Program (CICP),* HEALTH RESOURCES & SERVICES ADMIN. *available at* https://www.hrsa.gov/cicp.

the liability of the vaccine manufacturers by providing this separate process for adjudicating claims and shielding the manufacturers from lawsuits.[1424]

Below is a comparison table between the two programs which is featured HRSA's CICP webpage and has been simplified here.[1425]

	CICP	VICP
Filing Deadlines	• One (1) year filing deadline • Filing deadline when a countermeasures injury table is developed or changed	• Injury claim filing deadline • Death claim filing deadline • Filing deadline when changes are made to the Vaccine Injury Table
Process for Adding Covered Vaccines/ Countermeasures	Covered countermeasures are identified by the Secretary of HHS in declarations published under the PREP Act.	For a category of vaccines to be covered by the VICP, the category of vaccines must be recommended for routine administration to children and/or pregnant women by the Centers for Disease Control and Prevention, subject to an excise tax by federal law, and added to the Vaccine Injury Table by the Secretary of Health and Human Services. This has not been done for any U.S. licensed COVID-19 vaccines, which have not been developed to date.
Type of Injury Covered	Serious physical injuries, Deaths	Injuries with effects lasting for more than 6 months after the vaccine was given or resulted in inpatient hospitalization and surgery, or Deaths
Payment of Legal Fees and Costs	Attorneys' fees and costs are not paid by the program.	Attorneys' fees and costs may be available if certain requirements are met (petition filed in good faith and on a reasonable basis)
Process for Filing a Request/Petition	File the Request Form and documentation with the Secretary of HHS.	File petition and documentation with the U.S. Court of Federal Claims and the Secretary of HHS.
Process for Resolving Requests/ Petitions	Administrative Process	Judicial Process
Covered Injury Determinations	HHS makes decision.	Special Masters (or judges) of U.S. of Court of Federal Claims make decision.

[1424] CRS, The National Vaccine Injury Compensation Program and the Office of Special Masters (Sept. 14, 2022).
[1425] Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP), HEALTH RESOURCES & SERVICES ADMIN. *available at* https://www.hrsa.gov/cicp/cicp-vicp.

	CICP	VICP
Appeal Rights	One-step administrative reconsideration possible. No judicial appeal permitted.	Judicial appeal by either party to higher courts possible.
Program Funding	Appropriated Funds	Vaccine Injury Compensation Trust Fund

FINDING: The U.S. Government is Failing to Efficiently, Fairly, and Transparently Adjudicate Claims for COVID-19 Vaccine Injuries.

Because of CICP's limited resources, adjudication of claims is a lengthy process. HRSA reported that 10,226 of the 13,356 total COVID-19 claims are currently pending or are in review.[1426]

CICP Claims Data for COVID-19 Vaccines	
Claims filed	13,520
Claims pending or in review	10,082
Decisions	3,438
Claims compensated	18
Claims denied	3,373

These figures indicate that only 25 percent of all COVID-19 countermeasure claims have been adjudicated so far, with a denial rate of more than 98 percent. Worse still, the design differences also mean that it is much more difficult to be compensated via CICP and the payouts are significantly smaller. As of November 30, 2024, CICP only compensated 18 of the 65 COVID-19 claims it determined eligible for compensation, and the average award was only about $24,514. This also includes one extreme outlier award of more than $370,000, thus the median award is only $4,207. On the other hand, the average VICP payout over the last 35 years is approximately $468,000.[1427] The chart below highlights each of the compensated CICP claims for COVID-19 vaccines.[1428]

Countermeasure	Injury	Compensation Amount
COVID-19 Vaccine	Myopericarditis	$8,962
COVID-19 Vaccine	Myocarditis	$4,990
COVID-19 Vaccine	Myocarditis	$4,230
COVID-19 Vaccine	Myopericarditis	$4,183
COVID-19 Vaccine	Myocarditis	$1,583

[1426] *Countermeasures Injury Compensation Program (CICP) Data: Aggregate,* HEALTH RESOURCES & SERVICES ADMINISTRATION (Aug. 1, 2024) *available at* https://www.hrsa.gov/cicp/cicp-data.
[1427] *National Vaccine Injury Compensation Program: Monthly Statistics Report,* HEALTH RESOURCES & SERVICES ADMINISTRATION (Last updated Nov 1, 2024) available at https://www.hrsa.gov/vaccine-compensation/data.
[1428] *Countermeasures Injury Compensation Program (CICP) Data: Aggregate,* HEALTH RESOURCES & SERVICES ADMINISTRATION (Aug. 1, 2024) *available at* https://www.hrsa.gov/cicp/cicp-data.

COVID-19 Vaccine	Myocarditis	$1,033
COVID-19 Vaccine	Myocarditis	$12,403
COVID-19 Vaccine	Anaphylaxis	$2,020
COVID-19 Vaccine	Myopericarditis	$3,958
COVID-19 Vaccine	Myocarditis	$4,919
COVID-19 Vaccine	Myocarditis	$1,900
COVID-19 Vaccine	Myocarditis	$4,934
COVID-19 Vaccine	Myocarditis	$5,392
COVID-19 Vaccine	Myocarditis	$370,376
COVID-19 Vaccine	Syncope	$4,493
COVID-19 Vaccine	Myocarditis	$1,171
COVID-19 Vaccine	Myocarditis	$1,161
COVD-19 Vaccine	Guillain-Barre Syndrome	$3,546

As indicated above, claims made under VICP are adjudicated via a judicial process in the US Court of Federal Claims. Meanwhile, claims made under the CICP are adjudicated by an administrative process that is managed by HRSA. The details of each CICP decision are not made public which means that the rationale of each case's compensation award or decision are indiscernible to the public and to other claimants in the program. This opacity means that the rationale of each case's compensation award or decision are indiscernible to the public and to other claimants in the program. For example, the CICP's rationale to award $370,376 for one myocarditis claim but $1,033 for another is unclear. While it is likely that the higher award was for a death claim, that is not explicitly noted, nor is it clear how that number was determined when the maximum award for a death claim is $437,503 for fiscal year 2024.[1429]

The nature of CICP being a HRSA administrative process also means that all decision-making authority ultimately lies with the HHS Secretary. Meanwhile, HHS acts as a fervent promotor of vaccines in general, including the COVID-19 vaccine. This situation calls into question whether countermeasures which were mandated by the government can be fairly adjudicated by an executive branch agency that is inexorably connected to such vaccine policy. This arrangement poses an apparent conflict of interest and may undermine public trust in the compensation process and in vaccines broadly.

The Select Subcommittee heard from several claimants to CICP who shared their personal experiences with the program. Mr. Cody Flint, a commercial agriculture pilot from Mississippi, explained how he experienced a severe adverse reaction to the Pfizer COVID-19 vaccine within 30 minutes of receiving it in February 2021. Mr. Flint was diagnosed with left

[1429] Countermeasure Injury Compensation Program, *Request for Benefits Form Instructions* (last updated Apr. 23, 2023) *available at* https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-request-form-instructions.pdf; Benefits by the Year, Public Safety Officers Benefits Program *available at* https://bja.ojp.gov/program/psob/resources/benefits-by-year#:~:text=Contact%20Us&text=The%20amount%20of%20the%20PSOB,October%201%2C%202023%20is%20%241%2C488.00 (PSOB indicates the FY2024 maximum is $473,503).

and right perilymphatic fistulas due to increased intracranial pressure and was unable to working as a pilot as a result.[1430]

Mr. Flint submitted a claim to CICP in April 2021 and did not receive any communication until Senator Cindy Hyde-Smith (R-M.S.) brought up his case to HHS Secretary Becerra during a Senate Appropriations Committee hearing on May 4, 2022.[1431] Two weeks after the hearing, Mr. Flint received a denial letter for his claim.[1432] The denial letter from HRSA indicated that CICP was not aware of any links between the Pfizer COVID-19 vaccine and intracranial pressure.[1433] Mr. Flint immediately submitted a reconsideration package which included a letter from his surgeon, but he received another denial letter a few months later. Unfortunately, unlike the VICP, the CICP's design does not permit judicial appeal.[1434] Therefore, individuals like Mr. Flint have little recourse if their claim is denied.

This is just one example, but many other people's experiences tell a similar story – that the program does not appear to be working sufficiently to achieve its aims. According to Ms. Renée Gentry, director of The George Washington University's Vaccine Injury Litigation Clinic who has represented numerous claimants, CICP provides "little more than the right to file and lose."[1435] If the government wishes to absolve manufacturers of liability and take over the role that the courts would typically provide, then it must facilitate a fair and robust process.

FINDING:	The Countermeasures Injury Compensation Program Failed to Handle a Mass-Vaccination Program.

The CICP was created to provide compensation benefits for injuries associated with countermeasures deployed to combat a public health emergency or security threat. While the U.S. certainly confronted serious public health threats before, the COVID-19 pandemic was a once-in-a-generation event that brought unprecedented challenges to many public health institutions and systems. Unfortunately, CICP appears to not be designed to handle compensation for a countermeasure which was as widely distributed as the COVID-19 vaccine.

As of August 1, 2024, the total number of claims ever filed to CICP is 13,920, and COVID-19 claims account for 13,356—more than 97 percent of the total. On February 15, 2024, CDR Reed Grimes testified about the challenges facing the program. CDR Grimes specifically noted this immense uptick in caseload in his opening statement.

CDR George Reed Grimes (February 15, 2024)

[1430] Cody Flint Letter (in possession of the Select Subcommittee)
[1431] A Review of the President's FY 2023 Funding Request and Budget Justification for the Dep't of Health and Human Services: Hearing Before U.S. Senate Comm. on Appropriations, 117th Cong. 2 (May 4, 2022).
[1432] Cody Flint Letter (in possession of Select Subcommittee)
[1433] *Id.*
[1434] *Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP),* HEALTH RESOURCES & SERVICES ADMIN.
[1435] Renée Gentry written testimony, VAERS Part II hearing, March 21, 2024.

While injuries are rare and these claims represent a small fraction of the approximately 676 million total COVID-19 vaccines that have been administered in the United States, the current caseload is of a different order than the previous volume of claims in the Program given the scale of the utilization of COVID-19 covered countermeasures.[1436]

Congresswoman Miller-Meeks questioned CDR Grimes about the cause of the backlog. CDR Grimes testified that the backlog was because the CICP only had four staff when the pandemic began.

CDR George Reed Grimes (February 15, 2024)

Q. I understand that there's a current backlog of claims in CICP by about more than 10,000. Why is there a backlog of claims for the COVID–19 vaccines?

A. Thank you for that question. So, at the beginning of the COVID–19 pandemic, we had not had a direct appropriation with the CICP. We also had only four staff. When we received our first direct appropriation in Fiscal Year 2022, we were able to ramp up quickly, and now we have over 35 staff who are assisting to adjudicate claims.[1437]

HRSA's updated figures indicate that as of August 1, 2024, there are 10,226 claims pending or under review.[1438] With the staff increased to 35, CDR Grimes testified that the number of claims resolved each month increased from an average of zero per month to an average of more than 90 per month:

CDR George Reed Grimes (February 15, 2024)

We've also implemented other key process improvements to resolve claims at a faster rate. In 2023, we averaged more than 90 claims resolved each month, which is up from zero per month the year before I started in this role.[1439]

However, even with this increased rate, the current backlog would take nearly a decade to eliminate without accounting for any new claims.[1440] It therefore appears that more must be done to streamline the process to ensure timely decisions. CDR Grimes additionally testified about CICP's efforts to establish an Injury Table for COVID-19 vaccines, which he argued would allow for a streamlined claims review process:

[1436] Commander Grimes written testimony, VAERS Part 1 hearing, February 15, 2024.
[1437] VAERS Part 1 hearing, February 15, 2024, page 35 of transcript
[1438] *Countermeasures Injury Compensation Program (CICP) Data: Aggregate,* HEALTH RESOURCES & SERVICES ADMINISTRATION (Nov. 1, 2024) *available at* https://www.hrsa.gov/cicp/cicp-data.
[1439] VAERS Part 1 hearing, February 15, 2024, Grimes opening statement, page 9 of transcript
[1440] 10,226 claims pending review / 90 per month = 113.6 months (Staff math)

CDR George Reed Grimes (February 15, 2024)

The CICP is also in the process of establishing an injury table for COVID–19 vaccine injuries that are presumed to be directly caused by a covered countermeasure. In order to establish this table, HHS must meet the high evidence standards set by Congress. The injury table is another tool that will allow us to streamline the claims review process and more expeditiously address requests.[1441]

This will be an important step toward improving efficiency. For claimants whose injuries appear on the injury table and were sustained within the relevant time window, CICP will automatically assume the injury was the direct result of the countermeasure.[1442] Whereas, for non-table injuries, the claimant must prove that the injury was a "direct result" of the countermeasure, based on "compelling, reliable, medical and scientific evidence."[1443] Thus, non-table injuries are significantly more complicated and time consuming to adjudicate, and act as yet another barrier to compensation for claimants.

As of September 12, 2024, it appears that HRSA has not established an injury table for COVID-19 countermeasures.[1444] Yet, since at least June 2021, the federal government acknowledges some conditions, such as Myocarditis, as known side effects of COVID-19 vaccines.[1445]

FINDING: A Robust and Transparent Vaccine Injury Compensation Program Is Necessary for Promoting Trust in Vaccines.

Regardless of any claims that COVID-19 vaccines are particularly dangerous, it appears that the federal government mandated them without an adequate system in place to adjudicate the inevitable injuries they cause. This may have significant effects on the trust of the public and damage confidence in vaccines. A June 2022 *Politico* article discussed how efforts in Congress to reform the "overwhelmed" system had failed so-far and highlighted the fact that this could fuel vaccine hesitancy.[1446] According to Dr. Renée Gentry, "the cost of [CICP's] failing will be like throwing kerosene on the antivax fire."[1447]

Dr. Woodcock agreed that adequate vaccine injury compensation is important, particularly in promoting confidence in vaccines:

[1441] Assessing America's Vaccine Safety Systems, Part 1, February 15, 2024, transcript page 13, Grimes opening statement
[1442] Kevin J. Hickey, et al., Cong. Research Servs., R46982, Compensation for COVID-19 Vaccine Injuries (Updated Mar. 31, 2023).
[1443] *Id.*
[1444] CICP aggregate data
[1445] Berkeley Lovelace, Jr., *CDC safety group says there's a likely link between rare heart inflammation in young people after Covid shot,* CNBC (June 23, 2021).
[1446] Lauren Gardner, *Vaccine injury compensation programs overwhelmed as congressional reform languishes*, POLITICO, (June 1, 2022).
[1447] *Id.*

Dr. Janet Woodcock (May 13, 2024)

Q. [D]o you agree that adequate and comprehensive compensation for individuals who experience rare but serious adverse events relating to vaccines is an important element of promoting confidence in vaccines?

A. I agree with that.

Q. Would you care to elaborate on why that is?

A. Because any medical intervention will cause some harm as well as some as well as major benefit. So the statutes say safe and effective, but safe really means relative to the magnitude of the benefit, not without any harm. So people who are taking vaccines are not only protecting themselves but doing it to protect others, and so forth. And my understanding is the Vaccine Incentive Compensation Act was passed in order to recognize that people can be harmed and to adequately compensate them and protect them.[1448]

On March 21, 2024, Dr. Gentry testified that the success of America's immunization programs relies on public confidence in vaccines.

Dr. Renee Gentry (March 21, 2024)

A critical part of vaccine confidence is ensuring that those rare individuals who are injured by vaccines have a reasonable and effective forum in which to make their claims.[1449]

To properly prepare for a future pandemic, it is critical that the federal government and public health officials foster trust in vaccines. No matter how safe a vaccine may be, trust cannot be adequately fostered without efficient and transparent compensation systems. Therefore, it appears that significant reform may be necessary.

FINDING: Debating or Discussing Vaccine Injury Compensation Is Not "Anti-Vax," and Implications Otherwise Are Counterproductive to Protecting Public Health.

It is paradoxical to imply that the vaccine injured are "anti-vax" since a person must be vaccinated to experience a serious adverse event. This fact was well defined by Dr. Gentry:

Dr. Renee Gentry (March 21, 2024)

[1448] Woodcock TI, *supra* note 1171, at 127-128.
[1449] Assessing America's Vaccine Safety Systems, Part II, March 21, 2024, Gentry opening statement

> [I]t is critical to distinguish the vaccine injured from the anti-vax. All of my clients were vaccinated. They suffered real and often catastrophic injuries that are supported by medical and scientific literature and expert opinion.[1450]

Dr. Gentry also argued that it is counterproductive to their goals for pro-vaccine advocates to use such pejoratives when discussing vaccine injury compensation, as it bolsters vaccine hesitancy.

> **Dr. Renee Gentry (March 21, 2024)**
>
> The well-meaning, the often dismissive and critical comments of the pro-vaccine side directed at those individuals asserting vaccine injury also creates and bolsters vaccine hesitancy in those individuals who were previously vaccinated and are pro-vaccine. The vaccine injured that I and my colleagues represent are not anti-vax.[1451]

This divisive language was a critical misstep of the COVID-19 vaccination campaign which alienated and dismissed people who had experienced rare but life-altering adverse reactions to the vaccine.

[1450] Assessing America's Vaccine Safety Systems, Part II, March 21, 2024, Gentry opening statement
[1451] Assessing America's Vaccine Safety Systems, Part II, March 21, 2024, Gentry opening statement

VIII. The Erosion of the Doctor-Patient Relationship During the COVID-19 Pandemic

Available data show the relationship between a physician and their patient is a key element to providing high quality care.[1452] A doctor knowing their patient and the nuance of the patient's medical history has extraordinary value. It allows the doctor to make informed decisions about patient care and more accurate diagnoses. This relationship is also essential in ensuring mutual trust and respect. Similarly, doctors must have the ability to seize upon the value of this relationship and make critical decisions, without outside interference.

In a 2006 legal opinion, an Illinois court defined the doctor-patient relationship as "a consensual relationship in which the patient knowingly seeks the physician's assistance and in which the physician knowingly accepts the person as a patient."[1453] However, this legalistic definition does little to properly explain what is so powerful and important about this dynamic. According to the American Medical Association [hereinafter "AMA"] code of ethics, this relationship is described as:

> The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.[1454]

A paper published in 2015 titled *Impact of the Doctor-Patient Relationship* identified the four elements that form the doctor-patient relationship as trust, knowledge, regard, and loyalty.[1455] The paper notes some of the powerful benefits a strong relationship can yield, including that "a physician's knowledge of the patient's ailments and emotional state is associated positively with whether or not those physical ailments resolve." The paper's conclusion was as follows:

> As our vignettes intended to illustrate, the doctor-patient relationship is a powerful part of a doctor's visit and can alter health outcomes for patients. Therefore, it is important for physicians to recognize when the relationship is challenged or failing. If the relationship is challenged or failing, physicians should be able to recognize the causes for the disruption in the relationship and implement solutions to improve care.[1456]

Since a doctor's direct relationship with their patient is such a significant aspect of health care delivery, it is therefore important that health care policies and systems prioritize and

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[1452] R. Henry Olaisen, *et al., Assessing the Longitudinal Impact of Physician-Patient Relationship on Functional Health*, ANNALS OF FAMILY MEDICINE (Sept. 18, 2020).
[1453] *QT, Inc. v. Jacksonville*, No. 05 C 6387 (N.D. Ill. May 15, 2006).
[1454] American Medical Association, Code of Medical Ethics, Opinion 1.1.1, Patient-Physician Relationships.
[1455] Fallon E. Chipidza, *et al., Impact of the Doctor-Patient Relationship*, PUBMED CENTRAL (Oct. 22, 2015).
[1456] *Id.*

preserve this relationship. As the American health care system continues to evolve to confront new challenges and utilize new technologies, it is ever important that we consider the human-to-human element and its direct link with positive health outcomes. This was a component of the global response to COVID-19 that was tragically ignored in favor of short-sighted one-size-fits-all solutions.

FINDING:	Pandemic-Era Policy Often Disregarded or Outright Violated the Sanctity of the Doctor-Patient Relationship.

Some of the most consequential decisions of the COVID-19 pandemic were surrounding COVID-19 vaccines. Unfortunately, government policy on this front violated the sanctity of the doctor-patient relationship and may have permanent consequences. One glaring example is the fact that hundreds of millions of doses of COVID-19 vaccines were distributed under a regulatory arrangement that did not ensure the same standards of informed consent that fully approved drugs are subject to.

Generally, informed consent is "the process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention."[1457] The American Medical Association (AMA) states "the process of informed consent occurs when communication between a patient and a physician results in the patient's authorization or agreement to undergo a specific medical intervention."[1458] The FDA's guidance documents indicate that informed consent "is not required for administration or use of an EUA product."[1459] During a transcribed interview conducted by Select Subcommittee staff, Dr. Woodcock readily admitted this fact:

Dr. Janet Woodcock (May 13, 2024)

Q. Does an EUA necessitate informed consent from individuals?

A. My understanding is it does not.[1460]

Dr. Woodcock testified that instead of the typical legal documents, there were "information sheets" given out for COVID-19 vaccines and therapeutics which "spelled out…what the parameters were."[1461] The CDC produces Vaccine Information Statements [hereinafter "VIS"] which Federal law requires healthcare staff provide to a patient, parent, or legal representative before each dose of certain vaccines.[1462] Because COVID-19 vaccines are

[1457] Parth Shah, *et al., Informed Consent*, StatPearls (Oct. 15, 2024).
[1458] American Medical Association, Code of Medical Ethics, Opinion 2.1.1, Informed Consent.
[1459] *Guidance Document: Emergency Use Authorization of Medical Products and Related Authorities*, U.S. Food & Drug Admin. (Jan. 2017).
[1460] Woodcock TI, *supra* note 1171, at 871-873.
[1461] Woodcock TI, *supra* note 1171, at 37.
[1462] *Vaccines & Immunizations*, Ctrs. For Disease Control and Prevention, *available at* https://www.cdc.gov/vaccines/hcp/about-vis/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html.

not covered under the National Childhood Vaccine Injury Act, healthcare staff are not required to provide VISs before administering COVID-19 vaccines.[1463]

Additionally, during the pandemic, vaccines were often administered at pharmacies rather than in a doctor's office or hospital. In August 2020, HHS issued an amendment to the PREP Act declaration which permitted State-licensed pharmacists to administer vaccines under certain circumstances.[1464] A January 2023 report on trends in vaccine administration found that "across all vaccines for adults in-scope, a large majority off the administration took place at the pharmacy level compared to a non-pharmacy medical setting…"[1465] This report did not factor in locations where claims wouldn't be generated, including mass vaccination centers which administered a significant share of COVID-19 vaccine doses early in the rollout.

While these flexibilities were ostensibly put in place to increase access to vaccines, they may have also served to further erode the role of doctors in these important medical decisions. Following HHS' August 2020 amendment, representatives of the AMA publicly urged HHS to "reconsider the negative health repercussions of funneling children away from their primary care physicians and rescind this declaration."[1466]

Worse, mandatory vaccination policies represented a direct assault on the doctor-patient relationship. Vaccine mandates may be the most salient example of pandemic-era policies where governments and other political entities inserted themselves in a decision that should be between each patient and their doctor. This is inherently incompatible with the definition of the doctor-patient relationship.

The COVID-19 vaccine mandates also largely ignored the notion of naturally acquired immunity. By the standard of most COVID-19 vaccine mandates, there was no exception made for those who had previously contracted the virus. The mandates also left no room for women who were pregnant or trying to get pregnant. If left up to doctors, who are familiar with their patients and their health, individual patient risk and benefit could have been much better assessed. During the Select Subcommittee's July 27, 2023 hearing on vaccine mandates, Chairman Wenstrup shared his own experience dealing with this one-size-fits-all approach:

> **Chairman Brad Wenstrup (July 27, 2023)**
>
> I got vaccinated, Pfizer, both doses. Six months later, I got COVID. The only reason I knew is I couldn't smell garlic salt. I was told I needed a booster to travel. I said I would like to check my T-cells and antibodies. The lab here couldn't do the T-cells. I got my antibodies. Strong number was 40. My number was 821. Should I get a booster? That is a legitimate question. I don't want a hyperimmune response.[1467]

[1463] Id.
[1464] Notice, Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, U.S. DEP'T OF HEALTH & HUMAN SERVICES (Aug. 24, 2020).
[1465] *Trends in Vaccine Administration in the United States*, THE IQVIA INSTITUTE (Jan. 13, 2023).
[1466] Andis Robeznieks, *AMA opposes HHS move to expand pharmacists' scope of practice*, AMA (Aug. 24, 2020).
[1467] Vaccine Mandates Hearing Transcript Page 42

Relatedly, some pandemic policies also created intense political pressure for doctors to toe the line and recommend COVID-19 vaccines and boosters regardless of whether they believed the evidence supported such a recommendation. Doctors saw colleagues who spoke out being ridiculed and silenced and many likely chose to keep their own dissent to themselves.[1468] Some medical boards and state governments took things even further and pursued legal and administrative action against doctors who were perceived to be purveying misinformation.[1469]

Dr. Azadeh Khatibi testified during the Select Subcommittee's September 14, 2023 hearing about the rigid anti-free speech policies which were imposed on medical providers in California during the pandemic.[1470] One such example was a California law signed by Governor Gavin Newsom in August 2022 which declared it to be "unprofessional conduct" for doctors to disseminate misinformation or disinformation about COVID-19, which was state-defined as "contradicted by contemporary scientific consensus contrary to the standard of care."[1471] Dr. Khatibi testified that, as a doctor in California, she believed that scientific consensus is "always behind the cutting edge" which is why doctors have historically "had liberty to contradict consensus opinion."[1472] California eventually repealed this law in October 2023 after mounting legal pressure, however significant damage had already been done.[1473]

Vaccine mandates were not only ineffective, but they were also harmful. As was established during the Select Subcommittee's July 2023 hearing on the subject, vaccine mandates caused significant collateral damage.[1474] A BMJ paper from May 2022 titled *The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good* found that COVID-19 vaccine mandates caused significant collateral damage. The paper's summary stated:

> Our analysis strongly suggests that mandatory COVID-19 vaccine policies have had damaging effects on public trust, vaccine confidence, political polarization, human rights, inequities and social wellbeing. We question the effectiveness and consequences of coercive vaccination policy in pandemic response and urge the public health community and policymakers to return to non-discriminatory, trust-based public health approaches.[1475]

[1468] Timothy Bella, *A vaccine scientist's discredited claims have bolstered a movement of misinformation*, THE WASH. POST (Jan. 24, 2022).
[1469] Alicia Ault, *ABIM Revokes Certification for Two Physicians Accused of COVID Misinformation*, MEDSCAPE (Aug. 15, 2024).
[1470] Oh Doctor, Where Art Thou? Pandemic Erosion of the Doctor-Patient Relationship: Hearing Before Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 1 (Sept. 14, 2023).
[1471] Steven Lee Myers, *California Approves Bill to Punish Doctors Who Spread False Information*, THE N.Y. TIMES (Aug. 29, 2022).
[1472] Oh Doctor, Where Art Thou? *Supra* note 18.
[1473] Sean Salai, *California repeals COVID misinformation law, bowing to legal pressure*, The Wash. Times (Oct. 2, 2023).
[1474] Because I Said So, *supra* note 1348.
[1475] Bardosh, The unintended consequences of COVID-19 vaccine policy, *supra* note 891.

The paper also asserts that these vaccine mandates may "be in tension with" bioethical principles:

> Denying individuals education, livelihoods, medical care or social life unless they get vaccinated—especially in light of the limitation with current vaccines—is arguably in tension with constitutional and bioethical principles, especially in liberal democracies. While public support consolidated behind these policies in many countries, we should acknowledge that ethical frameworks were designed to ensure that rights and liberties are respected even during public health emergencies.[1476]

During the Select Subcommittee's hearing on September 14, 2024, Dr. Jeffrey Singer—a surgeon who has written about medical ethics—testified that vaccine mandates hindered trust and undermined the doctor-patient relationship:

> **Dr. Jeffrey Singer (September 14, 2024)**
>
> Q. Finally, very simply, do you feel that vaccine mandates facilitate fracturing the patient-doctor relationship?
>
> A. I think mandating does because, first of all, it's a natural tendency for people to recoil when they're mandated even if what's being mandated is actually a good idea. People don't like being told they have to do things. And so, when you have somebody who it's important that they have a very trusting relationship, the doctor and the patient, and the patient understands that they're being compelled to do something, I think it just undermines the relationship of trust between the doctor and the patient.[1477]

Dr. Singer published a study titled "A Hippocratic Oath for a Free Society," wherein he argues that doctors must always "prioritize the autonomy and rights of individual patients" and should take an oath which declares:

> I will respect the crucial scientific advances in medicine but will always question the assumptions my profession has inherited and will judge them in the light of the latest evidence. I will gladly share any knowledge I have gleaned from years of research, study, and clinical experience with health professionals in all disciplines. I will respect my patients' autonomy, thoroughly explain all the diagnostic possibilities and therapeutic options as I understand them, offer my best opinion and advice from among these options, and accept their decisions.[1478]

[1476] *Id.*
[1477] Because I Said So, *supra* note 1348, at 35.
[1478] *Id*. (statement by Jeffrey A. Singer, M.D.).

When asked to expand on his study on the Hippocratic Oath, Dr. Singer testified that he did not believe the government had the right to compel vaccination:

Dr. Jeffrey Singer (September 14, 2024)

Q. Dr. Singer, you have written about the ethical questions of COVID–19 vaccine mandates, and you have often said, and I'm quoting at this point, as a medical doctor, I enthusiastically endorse COVID–19 vaccine, and you personally had been vaccinated and will encourage others to be vaccinated. But you continued brilliantly by saying, but I will use persuasion, not coercion. Your words. Dr. Singer, do you believe that vaccine mandates without exemption are incompatible with the Hippocratic oath or the tenets of the basic doctor-patient relationship?

A. Representative Joyce, Dr. Joyce, yes, I do. I think it's actually you have no right to force someone to be vaccinated. Obviously, I believe that the vaccines saved hundreds of thousands of lives, and I got vaccinated. I got the first two shots, and I got the booster shortly thereafter, and I'm glad I did. But my role is to recommend to people, not to force people, not to compel people. In addition, there are some people who have very good reasons to not be vaccinated. They may have allergies. They may have already had COVID, and they have natural immunity, and they are concerned about getting a reaction to a vaccine that is of a new technology and hadn't been subjected to clinical trials because there was an emergency use authorization. These are not unreasonable concerns. I need to respect those concerns.[1479]

Overall, Americans would be better served by a health care system that encouraged patients to seek out advice of a trusted doctor regarding their individual medical history and the risks and benefits of being vaccinated. This relationship between doctor and patient is a crucial cornerstone of overall trust in medicine and could have helped prevent some of the anti-science rhetoric and misinformation that erupted during the COVD-19 pandemic.

FINDING: The Use of Off-Label Prescriptions Was Unjustly Demonized and Further Eroded the Doctor-Patient Relationship.

The COVID-19 pandemic deepened political and social divides and opened new wounds in the public discourse. Unfortunately, health care was no exception. The onslaught of controversy, polarization, shame, and censorship damaged the profession as well as the health care system more broadly. One extremely common and important tool at the disposal of doctors is prescribing an FDA-approved medication for a use which the drug is not specifically approved

[1479] *Id.* at 34.

for—known as "off-label use." Studies have shown that up to 33 percent of all prescriptions in the U.S. are for off-label uses.[1480]

One reason why off-label use is so common is because of the difficulty for pharmaceutical companies to get a drug approved by the FDA for each possible indication, dose, patient population, etc. Thus, off-label usage of drugs is particularly important for those suffering with diseases or ailments for which there are few or even *no* approved treatments, especially rare diseases, or novel viruses.

However, during the pandemic, the off-label uses of possible treatments for COVID-19 were swiftly and systematically demonized. Doctors frequently reprimanded, threatened, censored, or even fired by their employers for doing so. The federal government weaponized public health agencies to promote fear surrounding drugs such as Ivermectin and Hydroxychloroquine. Most infamously, the FDA tweeted from its official Twitter (now X) account "You are not a horse. You are not a cow. Seriously, y'all. Stop it."[1481]

U.S. FDA
@US_FDA
You are not a horse. You are not a cow. Seriously, y'all. Stop it.
fda.gov
Why You Should Not Use Ivermectin to Treat or Prevent COVID-19
Using the Drug ivermectin to treat COVID-19 can be dangerous and even lethal. The FDA has not approved the drug for that purpose.
7:57 AM · Aug 21, 2021

This tweet seemingly conflated the off-label prescription of Ivermectin as being the same as humans intentionally taking the veterinary version of the drug without a doctor. In doing so, the FDA politicized the issue, forever poisoning any future discussion about the veracity of claims that any repurposed drugs may be effective against COVID-19. Similarly, on August 29, 2021, Dr. Fauci appeared on CNN's State of the Union with Jake Tapper and failed to correct Mr. Tapper's implication that Ivermectin is only a "anti-parasite horse drug."[1482]

Dr. Anthony Fauci (August 29, 2021)

[1480] Gail A. Van Norman, *Off-Label Marketing of Drugs*, PUBMED CENTRAL (Feb. 8, 2023).
[1481] Jen Christensen, *FDA settles lawsuit over ivermectin content that doctors claimed harmed their practice*, CNN (Mar. 27 2024).
[1482] State of the Union, CNN (Aug. 29, 2021).

Q. Poison control centers are reporting that their calls are spiking in places like Mississippi and Oklahoma because some Americans are trying to use an anti-parasite horse drug called Ivermectin to treat coronavirus, to prevent contracting coronavirus. What would you tell someone who's considering taking that drug?

A. Don't do it. There's no evidence whatsoever that that works, and it could potentially have toxicity, as you just mentioned, with people who've gone to poison control centers because they've taken the drug at a ridiculous dose and wind up getting sick. There's no clinical evidence that indicates that this works.[1483]

This campaign against certain off-label prescriptions, specifically Ivermectin, has also been the subject of litigation. On September 1, 2023, the U.S. Court of Appeals for the Fifth Circuit revived a lawsuit from a group of doctors who argued their reputations were unduly harmed by the FDA's actions, with one of the judges writing "[t]he Doctors have plausibly alleged that FDA's Posts fell on the wrong side of the line between telling about and telling to."[1484] Ultimately, as part of a settlement, the FDA agreed to delete and not repost this tweet (and several related social media posts) and retire the consumer update article originally posted on March 5, 2021.[1485]

During the Select Subcommittee's September 14, 2023 hearing, Dr. Jerry Williams testified that prescribed medications off-label many times before and during the COVID-19 pandemic, including Ivermectin and Hydroxychloroquine.[1486] He also testified that he believed the government's pressure campaign had made them more difficult to obtain.

Dr. Jerry Williams (September 14, 2023)

Q. Do you believe that actions taken by the FDA or other Federal officials may have caused this?

A. Yes. Without question.[1487]

In his opening statement, Dr. Williams testified how when the pandemic began, his quiver of "arrows" to fight the virus consisted of only one—Zinc tablets from his local pharmacy.[1488] When an in-vitro study was published in March of 2020 showing that hydroxychloroquine may be effective in the inhibition of SARS-CoV-2, Dr. Williams began preparing a treatment protocol for COVID-19 patients:

[1483] *Id.*
[1484] Kevin McGill, *Court revives doctors' lawsuit saying FDA overstepped its authority with anti-ivermectin campaign*, ASSOCIATED PRESS (Sept. 1, 2023).
[1485] Paul Bond, *FDA Settles Lawsuit over Ivermectin Social Media Posts*, NEWSWEEK (Mar. 22, 2024).
[1486] *See generally*, Oh Doctor, Where Art Thou? Pandemic Erosion of the Doctor-Patient Relationship: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 1, (Sept. 14, 2023) [hereinafter "Oh Doctor, Where Art Thou?"].
[1487] *Id.*
[1488] *Id.* at 14.

Dr. Jerry Williams (September 14, 2023)

We never attempted to do a publishable study. Our goal was to kill this virus and save the next patient coming through the door. We never took a one-size approach fits all. We treated each patient with as much of our protocol as was appropriate and safe and our anecdotal evidence accrued.

In summary, I simply adhered to my Hippocratic oath and a basic tenet of medicine, specifically infectious disease medicine—which the medical-industrial complex and bureaucracy asked us to all forget—treat early to prevent the afflicting agents, whether bacterial, viral, fungal, or protozoal from getting a toehold.

I rolled up my sleeves and applied what I had learned, was transparent and honest with my patients, observed carefully, followed up and documented compulsively, adjusted when necessary, learned to unlearn, and refused that which was antithetical to medical science.[1489]

In his written statement, Dr. Williams further testified how once the EUA for Hydroxychloroquine was revoked by the FDA and pharmacy boards began threatening pharmacists for filling prescriptions, it became difficult to obtain off-label drugs to treat his desperate patients. Dr. Williams testified:

Dr. Jerry Williams (September 14, 2024)

Pharmacists had always been my partners, my teammates, in rendering care to my patients. But that changed soon as well during the pandemic when the EUA for hydroxychloroquine was revoked by the FDA. With the government's misinformation campaigns, pharmacy Boards sending threatening letters to pharmacists, some soon started refusing to fill hydroxychloroquine prescriptions. I had the off-label discussions with my patients.

As a child neurologist, I was used to this because many drugs are delayed or never get FDA approval in children. All risks and benefits were discussed and the patient made an informed decision yet pharmacists started dishonoring the doctor-patient relationship. Pharmacy Boards in states such as Washington and others instructed pharmacists to report doctors for prescribing hydroxychloroquine and ivermectin for off-label use. Pharmacists were for the first time in my career not my teammates and partners, they were my potential adversaries. Another hurdle to cross to get

[1489] *Id.* at 15.

my patients the medications and care they desperately needed and wanted.[1490]

During the Select Subcommittee's September 14, 2023 hearing, Dr. Singer testified that approaches like Dr. Williams' are important because they are how the clinical field gains scientific knowledge:

Dr. Jeffrey Singer (September 14, 2024)

Q. Dr. Singer, why is it important to preserve a doctor's right to prescribe medications off-label?

A. Well, first of all, much of clinical knowledge comes from prescribing drugs off-label. We read in the medical literature much of the time comparative effectiveness studies showing how different drugs that were developed for one particular disease appear to have a use in another disease…this is the way we gain scientific knowledge in the clinical field. You really can't gain knowledge unless you try different things and report on it to your colleagues.[1491]

[1490] *Id*. (written testimony of Dr. Jerry Williams, M.D.).
[1491] *Id*. at 22.

The Economic Impact of the Coronavirus Pandemic and Associated Government Response on Individuals, Communities, Small Businesses, Health Care Providers, States, and Local Government Entities

The COVID-19 pandemic had profound economic impacts across the U.S., affecting individuals, communities, small businesses, healthcare providers, and state and local governments.

Americans faced widespread job losses, reduced income, and financial insecurity, particularly among low-wage workers and minorities. Government responses, including enhanced unemployment benefits, stimulus payments, and eviction moratoriums provided critical relief but also sparked debates about long-term economic dependency and labor shortages.

Communities experienced disruptions in daily life, with heightened economic inequality and strained social services. The pandemic deepened existing disparities, especially in low-income and minority communities, where access to healthcare and financial resources was limited.

Small businesses were hit hardest, particularly those in the retail, hospitality, and entertainment sectors. Many faced closures or severe revenue losses. Government interventions such as the PPP and EIDL offered lifelines, yet challenges in accessing funds and adapting to new market conditions led to widespread permanent closures.

Healthcare providers were overwhelmed by the surge in COVID-19 cases, leading to financial strain from increased operational costs and postponed elective procedures. Government support included emergency funding and cutting unnecessary red tape, but the sector still faced significant challenges, including supply shortages and staff burnout.

State and local governments faced declining tax revenues and increased demand for public services, forcing budget cuts and layoffs. Federal aid packages provided some relief, but the financial pressures exposed vulnerabilities in public sector funding and highlighted the need for more sustainable fiscal policies.

Overall, the pandemic underscored the importance of preparedness, resilience, and access to resources, with the U.S. government's response playing a crucial role in mitigating the worst economic impacts while also revealing areas for improvement in crisis management and support distribution.

I. The COVID-19 Pandemic's Impact on American Business

The COVID-19 pandemic was an unprecedented global health crisis that triggered profound economic disruption. Businesses around the world faced severe challenges as governments-imposed lockdowns, travel restrictions, and social distancing measures to contain the spread of the virus. These public health responses had devastating economic consequences, forcing millions of businesses to close temporarily or permanently. The scale of business

closures during the COVID-19 pandemic was immense, with numerous sectors facing reduced demand, forced shutdowns, and operational constraints. Small and medium-sized enterprises (SMEs), in particular, bore the brunt of the crisis, given their limited financial resources and reduced ability to withstand prolonged periods of low or no revenue.

FINDING:	Government Imposed Mandatory Lockdowns Were the Primary Cause of Temporary and Permanent Business Closures, but Other Factors Contributed as Well.

By the end of August 2020, industry survey data showed a staggering 163,735 U.S. businesses closed due to the pandemic, with 60 percent (97,966) of those closures classified as permanent.[1492] Having almost 100,000 businesses unable to reopen during the recovery phase represents a significant portion of the U.S. business landscape. The impact of business closures varied across sectors. The hospitality and food service industries were particularly hard-hit. According to a National Restaurant Association report in December 2020, 17 percent of the country's restaurants had closed long term or permanently.[1493] Similarly, the retail industry experienced widespread closures as foot traffic in brick-and-mortar stores plummeted due to lockdowns and the shift to online shopping.[1494] These closures had far-reaching effects on employment, local economies, and the overall business environment, resulting in significant long-term consequences.

While many businesses initially hoped to reopen once restrictions were lifted, several factors contributed to many closures becoming permanent.

One of the primary reasons for permanent closures was the extended duration of government-mandated lockdowns.[1495] As businesses were forced to remain closed for months, they experienced a sharp decline in revenue, while many still had to cover fixed costs such as rent, utilities, and payroll. According to the U.S. Bureau of Labor Statistics, during 2020 80 percent of businesses that were subjected to mandatory government mitigation measures told employees not to work or reduced hours compared to 54 percent of businesses that were not subjected to government-mandated mitigation measures.[1496] Additionally, according to the Small Business Pulse Survey conducted by the U.S. Census Bureau, 31 percent of small businesses reported that social distancing measures significantly reduced their revenue in 2020, leading many to furlough or lay off workers.[1497] This financial strain was particularly acute for SMEs,

[1492] Anjali Sundaram, *Yelp data shows 60% of business closures due to the coronavirus pandemic are now permanent*, CNBC (Sept. 16, 2020).
[1493] *Restaurant Industry in Free Fall; 10,000 Close in Three Months,* Nat'l Restaurant Association (Dec. 7, 2020).
[1494] Erin Gilliam Haije, *How the Retail Industry Has Been Affected by The Global Pandemic*, MOPINION (Jan. 28, 2021).
[1495] *See generally,* Steve Cuozzo, *Years after the end of COVID, NYC remains trapped in 'Long Lockdown'*, N.Y. POST (June 22, 2024); Joe Nocera & Bethany McLean, *COVID Lockdowns Were a Giant Experiment. It Was a Failure. A key lesson of the pandemic*, N.Y. MAGAZINE (Oct. 30, 2023).
[1496] U.S. BUREAU OF LAB. STAT., RESULTS OF THE 2020 BUSINESS RESPONSE SURVEY (2020).
[1497] Jane Callen, *Weekly Census Bureau Survey Provides Near-Real-Time Info on Businesses*, U.S. CENSUS BUREAU (May 14, 2020).

which often lacked the cash reserves to sustain operations for an extended period without income.

The uncertainty surrounding the pandemic further exacerbated the situation. With no clear timeline for when restrictions would ease or when consumer demand would return, many business owners faced difficult decisions about whether to continue operating or shut down permanently. The lack of clarity on how long the pandemic would last made it challenging for businesses to plan for the future or secure loans to stay afloat.

While government shutdowns played a primary role in closing businesses, the pandemic also caused a dramatic shift in consumer behavior, with long-lasting implications for businesses that remained open. As people stayed home to minimize their exposure to the virus, demand for certain goods and services plummeted, while online shopping, delivery services, and remote work gained popularity. Brick-and-mortar stores, restaurants, entertainment venues, and personal service businesses such as salons and gyms suffered as foot traffic dried up. By mid-2020, 75 percent of U.S. consumers tried a new shopping behavior, such as purchasing from a different brand or retailer, due to the pandemic.[1498]

Many of these behavioral shifts are expected to persist post-pandemic, leaving businesses that rely on in-person interactions—particularly small local businesses—struggling to adapt. The acceleration of e-commerce further displaced traditional retail models, leading to the permanent closure of numerous small businesses that could not compete with larger online platforms or afford the necessary technological investments to pivot to digital sales.[1499]

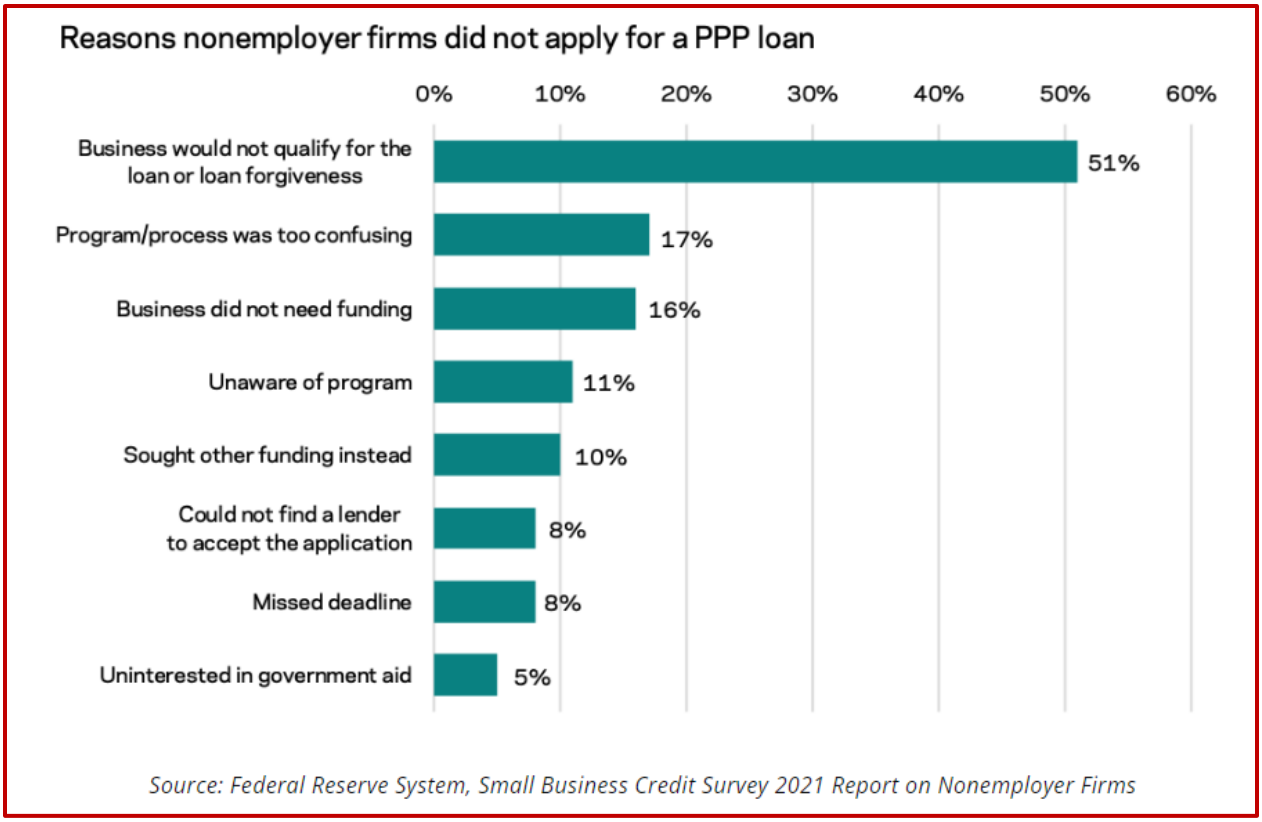
While governments around the world introduced relief packages to support businesses during the pandemic, these measures were often insufficient to stave off permanent closures. In the U.S., programs like PPP offered critical financial assistance to small businesses, allowing them to retain employees and cover operational costs. However, many businesses found the aid inadequate, especially as the pandemic persisted longer than expected. Additionally, not all businesses were able to access financial support due to bureaucratic hurdles, eligibility criteria, or the speed at which funds were distributed.[1500]According to a compilation of government surveys, 65 percent of "nonemployer" (very small) business owners reported that they did not apply for PPP because they assumed they would not qualify, or the process was too confusing.[1501]

[1498] Tamara Charm*, et al., The great consumer shift: Ten charts that show how U.S. shopping behavior is changing,* McKinsey & Co. (Aug. 4, 2020).

[1499] *Impact of COVID Pandemic on eCommerce,* Int'l Trade Administration, *available at* https://www.trade.gov/impact-covid-pandemic-ecommerce (last visited Oct. 21, 2024).

[1500] Alexander W. Bartik*, et al., The impact of COVID-19 on small business outcomes and expectations*, PNAS (July 10, 2020).

[1501] Emily Garr Pacetti & Maria Thompson, *Smallest Firms Reveal Barriers to Economic Inclusion: Lessons from Pandemic Support Programs*, Economic Innovation Group (Nov. 5, 2021) (Many nonemployers reported uncertainty about the different programs and eligibility requirements, or they lacked banking relationships necessary to secure funding. For the PPP specifically, 57 percent of nonemployer firms received the full funding amount they sought, compared to 77 percent of employer firms. Of the 65 percent of nonemployers who did *not* apply for the PPP, the most cited reasons were that the owner expected that the "business would not qualify for a loan or for loan forgiveness" and "the program/process was too confusing.).



The challenges in securing financial aid, combined with ongoing expenses and uncertain future revenue, led many business owners to make the difficult decision to close permanently.

FINDING:	Business Closures Disproportionately Impacted Rural and Low-Income Areas and Have Led to Long-Term Changes in These Areas.

While all regions faced economic challenges, the impact was not evenly distributed. Business closures disproportionately affected rural and low-income areas, exacerbating existing socioeconomic disparities and leaving lasting consequences.

Although businesses in urban and affluent areas also suffered during the pandemic, rural and low-income communities faced unique vulnerabilities that made them more susceptible to prolonged economic distress. Limited access to capital, dependence on small businesses, and fewer alternative employment opportunities amplified the negative effects of COVID-19-related shutdowns in these areas.

According to the Federal Reserve Board, approximately 400,000 businesses expected to close permanently during the first year of the pandemic in the U.S., driven primarily by the economic shock from COVID-19.[1502] While businesses across all sectors and geographies were affected, the burden fell disproportionately on small enterprises and those located in rural and

[1502] Leland D. Crane, *et al., Business Exit During the COVID-19 Pandemic: Non-Traditional Measures in Historical Context* at 5, FINANCE AND ECONOMICS DISCUSSION SERIES (Apr. 2021).

low-income areas as businesses in rural and low-income communities faced higher rates of closure than their urban counterparts.[1503] A survey conducted by Main Street America found that, by mid-2020, nearly 7.5 million small businesses in rural areas were at risk of permanent closure, with an estimated 34 percent of small business owners in these areas predicting they would not survive past the year.[1504]

Businesses in rural and low-income areas are often more reliant on certain sectors like agriculture, manufacturing, retail, and service industries, all of which were hard-hit by the pandemic. A National Bureau of Economic Research [hereinafter "NBER"] report found that rural and low-income regions were disproportionately affected by closures in hospitality, retail, and local services, which form the backbone of many local economies.[1505]

The heightened vulnerability of rural and low-income areas to business closures during the pandemic can be attributed to several structural and economic factors.

One of the most significant challenges faced by businesses in rural and low-income communities was limited access to financial resources. Small businesses in these areas often lacked relationships with large banks or financial institutions, making it more difficult to secure loans or government aid. Data from SBA reveals that businesses in wealthier, urban areas were more likely to receive PPP loans during the pandemic than those in rural and low-income areas.[1506] Counties with the lowest median incomes received less than half the per capita aid compared to wealthier counties.[1507] This disparity was even more pronounced in rural areas, where many small businesses struggled to access the application process due to lack of digital infrastructure or access to financial advisors.

Without sufficient access to financial assistance, many small businesses in these areas were unable to maintain operations during prolonged shutdowns. As a result, rural and low-income communities experienced higher rates of business closures, further slowing their economic recovery.

Rural and low-income communities are often more dependent on small, local businesses to provide employment and essential services. In contrast to urban areas with diverse economies, these communities tend to rely on a limited number of industries and businesses. The closures of

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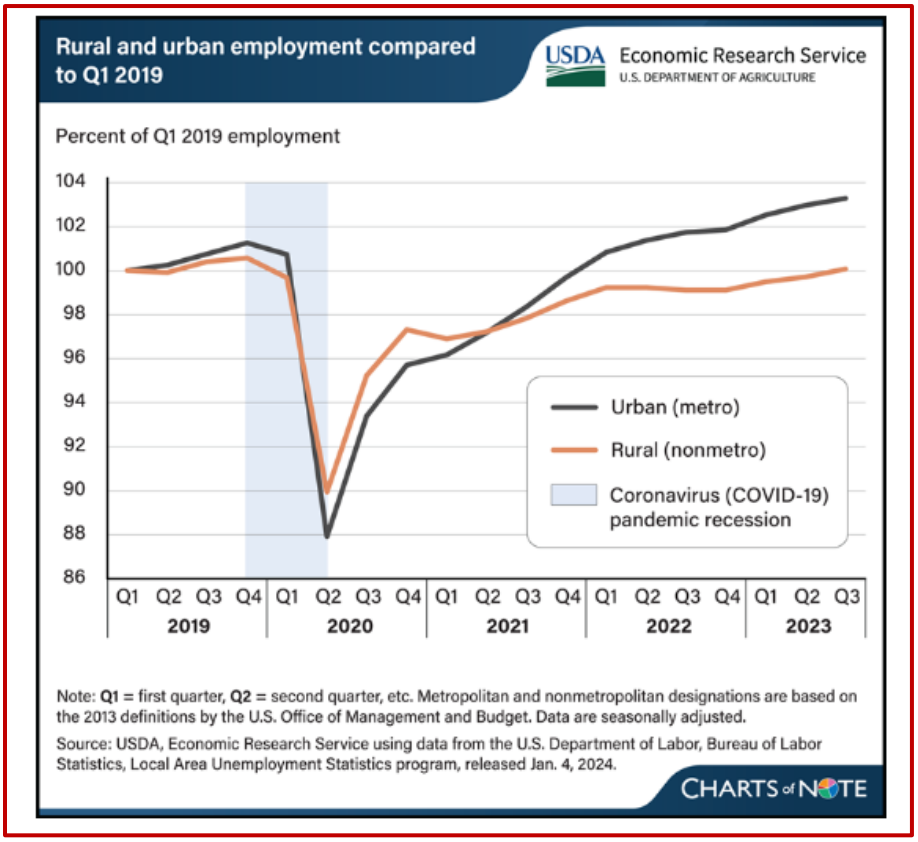
[1503] Hanna Love & Mike Powe, *Rural small businesses need local solutions to survive*, BROOKINGS INSTITUTION (Dec. 1, 2020).
[1504] Michael Powe & Matthew Wagner, *The Impact of COVID-19 on Small Businesses, Findings from Main Street America's Small Business Survey*, NATIONAL MAIN STREET CENTER (2020).
[1505] Yoshie Sano & Sheila Mammen, *Mitigating the Impact of the Coronavirus Pandemic on Rural Low-Income Families*, J FAM ECON ISSUES (Feb. 22, 2022); Ariadna Capasso, *et al., Socioeconomic predictors of COVID-19-related health disparities among United States workers: A structural equation modeling study*, PLOS GLOB. PUBLIC HEALTH (Feb. 9, 2022).
[1506] Jamie Smith Hopkins, *et al., PPP loans were supposed to prioritize low-income areas during the pandemic. They didn't.*, THE CTR. FOR PUBLIC INTEGRITY (Dec. 11, 2020).
[1507] Garrett Borawski & Mark E. Schweitzer, *How Well Did PPP Loans Reach Low- and Moderate-Income Communities?,* FED. RESERVE BANK OF CLEVELAND (May 27, 2021).

key local businesses, such as grocery stores, restaurants, and manufacturing facilities, had a ripple effect on the entire community.

Many rural and low-income areas had higher unemployment rates even before the pandemic. The pandemic exacerbated these trends, with rural counties experiencing some of the steepest employment declines. As local businesses closed permanently, the loss of jobs hit these communities particularly hard, as there were fewer alternative employment options. While urban areas were much quicker to recover jobs, rural areas have returned employment to pre-pandemic numbers within the last year. [1508]


Rural and urban employment compared to Q1 2019
USDA Economic Research Service
U.S. DEPARTMENT OF AGRICULTURE
Percent of Q1 2019 employment
104
102
100
98
96
94
92
90
88
86
Urban (metro)
Rural (nonmetro)
Coronavirus (COVID-19) pandemic recession
Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3
2019
2020
2021
2022
2023
Note: Q1 = first quarter, Q2 = second quarter, etc. Metropolitan and nonmetropolitan designations are based on the 2013 definitions by the U.S. Office of Management and Budget. Data are seasonally adjusted.
Source: USDA, Economic Research Service using data from the U.S. Department of Labor, Bureau of Labor Statistics, Local Area Unemployment Statistics program, released Jan. 4, 2024.
CHARTS of NOTE

The closure of local businesses also affected residents' access to essential services such as healthcare, groceries, and childcare. The closure of rural grocery stores and retail outlets left many low-income residents facing "food deserts" and longer travel times to obtain basic necessities.[1509] This further intensified the economic hardship experienced in these communities.

The digital divide—characterized by unequal access to high-speed internet and technology—worsened the impact of the pandemic on businesses in rural and low-income areas. With lockdowns forcing a rapid shift to online shopping, remote work, and e-commerce, many

[1508] *Rural employment has returned to pre-COVID-19 pandemic level,* U.S. DEP'T OF AGRICULTURE, *available at* https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=108586 (last updated Feb. 21, 2024).
[1509] Stacy Mitchell, *Fighting Monopoly Power*, INSTITUTE FOR LOCAL SELF-RELIANCE (July 2020).

small businesses in these communities struggled to adapt. Approximately 22 percent of rural Americans lacked access to high-speed broadband internet in 2020, compared to just 6 percent in urban areas.[1510] This lack of digital infrastructure made it difficult for businesses in rural areas to pivot to e-commerce or offer remote services, putting them at a competitive disadvantage. Low-income businesses, even in urban areas, also faced similar challenges due to the costs associated with upgrading technology and infrastructure.

While larger companies and urban-based businesses were able to quickly transition to online platforms, businesses in rural areas often lacked the resources and technical expertise to do so. As a result, many rural and low-income businesses missed out on the surge in e-commerce demand that occurred during the pandemic, contributing to their closure. Less than 50 percent of rural small businesses have an online sales presence, further reducing their ability to generate revenue during the pandemic.[1511]

The closure of businesses in rural and low-income areas has deepened pre-existing economic inequalities. Many of these regions have seen slower economic recovery compared to wealthier urban areas, further widening the economic gap. Rural and low-income areas experienced slower growth during the post-pandemic recovery period compared to urban areas.[1512] According to the Economic Innovation Group [hereinafter "EIG"], nearly 50 percent of rural counties saw slower employment recovery between 2021 and 2023, and many continue to experience higher unemployment rates and slower business re-openings.[1513] With fewer employment opportunities and the permanent closure of small businesses, poverty rates have surged in rural and low-income areas.

In rural and low-income communities, small businesses are not just economic entities; they are integral to the social and cultural fabric of the area. The loss of these businesses has had profound effects on community cohesion and local identity. The closure of local businesses—such as restaurants, shops, and community centers—has diminished the sense of community in many rural and low-income areas. These businesses often served as gathering places for residents, and their absence has left many communities feeling more isolated and fragmented. The closures of small businesses also reduced local tax revenue, leading to cuts in public services such as education, healthcare, and infrastructure maintenance.[1514]

While some rural and low-income communities have begun to recover, the long-term effects of business closures continue to pose significant challenges for economic revitalization.

[1510] Letter from Michael Cloud, *et al.,* Ranking Member, Subcomm. On Economic and Consumer Policy, to Jessica Rosenworcel, Acting Chairwoman, U.S. Fed. Communications Commission (Oct. 21, 2021); Emily A. Vogels, *Some digital divides persist between rural, urban and suburban, America*, PEW RESEARCH CENTER (Aug. 19, 2021).
[1511] *Unlocking the Digital Potential of Rural America*, U.S. CHAMBER TECHNOLOGY ENGAGEMENT CTR., *available at* https://americaninnovators.com/wp-content/uploads/2019/03/Unlocking-the-Digital-Potential-of-Rural-America.pdf (Mar. 2019) (About one-third of rural small businesses sell their products and services through their own websites and nearly 13% sell their products and services through third-party websites).
[1512] Ira Regmi, *How Topline Economic Indicators-like Low Unemployment-Miss Struggling Communities,* ROOSEVELT INSTITUTE (Jan. 16, 2024).
[1513] August Benzow, *Economic Renaissance or Fleeting Recovery? Left-Behind Counties See Boom in Jobs and Businesses Amid Widening Divides*, ECONOMIC INNOVATION GROUP (July 8, 2024).
[1514] Alana Semuels, *All the Way Retail's Decline Could Hurt American Towns*, THE ATLANTIC (May 23, 2017).

Without robust investment in local businesses and infrastructure, many areas face an uphill battle in rebuilding their economies. Economists emphasize the need for targeted investment in rural and low-income areas to support business creation, job training, and infrastructure development. According to a report by the Harvard Business Review, revitalizing these areas will require greater federal and state support, including grants and loans for small businesses, improved digital infrastructure, and policies that encourage entrepreneurship in underserved regions.[1515]

The COVID-19 pandemic disproportionately impacted businesses in rural and low-income areas, leading to higher rates of permanent closures and deeper economic distress. These communities faced unique challenges, including limited access to financial resources, dependence on small businesses, and a lack of digital infrastructure, all of which exacerbated the effects of the pandemic. The economic disparities created or worsened by these closures continue to shape the recovery process, leaving rural and low-income areas struggling to regain their economic footing. To address these challenges, targeted investment, equitable access to financial resources, and digital infrastructure improvements are essential

FINDING: The Lack of Supply Chain Diversity Exacerbated Economic and Business Recovery.

The COVID-19 pandemic exposed critical vulnerabilities in global supply chains, disrupting industries and economies around the world. In the U.S., the pandemic underscored the risks of highly concentrated and poorly diversified supply chains, leading to prolonged economic instability, shortages of essential goods, and widespread business closures. Supporting data is used to illustrate how these supply chain failures led to lasting consequences for American businesses and the broader economy.

Before the pandemic, global supply chains were structured for efficiency, with a focus on minimizing costs, maximizing profit margins, and just-in-time inventory management. However, this focus on efficiency left many industries, especially in the U.S., vulnerable to disruptions. A lack of geographical and supplier diversity, overreliance on single regions or countries, and limited inventory reserves created fragile systems that could not withstand the shock of the pandemic.

Certain sectors in the U.S. were particularly reliant on concentrated supply chains, which contributed significantly to economic disruptions during the pandemic. The pandemic highlighted the U.S.'s reliance on a small number of countries, particularly China and India, for essential medical supplies and pharmaceuticals. According to the FDA, approximately 72 percent of active pharmaceutical ingredients used in U.S. drug manufacturing are sourced from

[1515] Suntae Kim & Anna Kim, *Research: How Entrepreneurship Can Revitalize Local Communities*, HARVARD BUSINESS Review (Jan. 17, 2022).

overseas, primarily from China and India.[1516] When these countries imposed export restrictions, the U.S. faced critical shortages of PPE, ventilators, and other essential medical supplies.[1517]

Similarly, the automotive and electronics industries experienced severe supply chain disruptions due to their heavy reliance on components sourced from a limited number of regions. The semiconductor shortage, which began in 2020 and persisted into 2022, severely affected the automotive industry.[1518] U.S. auto production reduced by 1.3 million vehicles in 2021 due to semiconductor shortages, leading to billions in lost revenue and job cuts across the industry.[1519]

The COVID-19 pandemic quickly exposed the fragility of these concentrated supply chains, causing widespread disruptions in production and distribution. Factories in key manufacturing regions were forced to shut down, transportation networks were disrupted, and logistical bottlenecks arose, leading to shortages and delays across a wide range of industries.

The initial wave of COVID-19 forced factories in China, which manufactures nearly 30 percent of the world's goods according to the World Bank, to close or reduce production.[1520] This caused immediate disruptions in the global flow of goods. Companies that relied heavily on Chinese suppliers for components, including tech, apparel, and consumer goods industries, faced significant production delays. The Institute for Supply Management reported in March 2020 that nearly 75 percent of U.S. companies experienced supply chain disruptions due to the pandemic, with more than half of those companies facing operational delays of several weeks or longer.[1521]

The pandemic caused widespread disruptions to global shipping and transportation networks, further exacerbating supply chain challenges. Port closures, a shortage of shipping containers, and reduced air and sea freight capacity caused massive delays in the movement of goods. By mid-2021, the cost of shipping a container from China to the U.S. had surged by more than 400 percent, leading to increased costs for businesses and consumers alike.[1522] These delays resulted in inventory shortages for numerous businesses, forcing many to shut down or scale back operations due to a lack of available products.

The pandemic revealed that many U.S. companies had not diversified their supply chains adequately, creating systemic risks for their operations. Overreliance on a few suppliers or

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[1516] Safeguarding Pharmaceutical Supply Chains in a Global Economy: Hearing Before Subcomm. on Health, H. Comm. on Energy and Commerce, 116th Cong. (Oct. 30, 2019) (Testimony of Dr. Janet Woodcock, Dir. of the Center for Drug Evaluation and Research, Food and Drug Admin.).

[1517] Chrisine Ngoc Ngo & Huong Dang, *COVID-19 in America: Global supply chain reconsidered*, WORLD ECON (July 26, 2022), *see generally,* Chad P. Bown, *COVID-19: China's exports of medical supplies provide a ray of hope*, PIIE (Marh. 26, 2020); Simon Evenett, *et al., Trade policy responses to the COVID-19 pandemic crisis: Evidence from a new data set*, WORLD ECON (Mar. 15, 2021).

[1518] Darin Iraj, *The Ongoing Semiconductor Chip Shortage and the Sustainability of the Automotive Industry's Profit Boom: Outlook for 2023 and Beyond,* WESLEYAN BUSINESS REVIEW (Dec. 3, 2023).

[1519] Jack Ewing & Neal E. Boudette, *A Tiny Part's Big Ripple: Global Chip Shortage Hobbles the Auto Industry*, THE N.Y. TIMES (Apr. 23, 2021, last updated Oct. 14, 2021).

[1520] *China is the world's factory, more than ever*, THE ECONOMIST (Sept. 8, 2021).

[1521] *75% of Companies See Supply Chain Distributions Due to* Coronavirus, INSTITUTE FOR SUPPLY MANAGEMENT (Apr. 14, 2020).

[1522] Eric Kulisch, *Are you shipping me?!? $32,000 container move from China to LA*, FREIGHT WAVES (July 30, 2021).

countries for critical components led to a concentration of risk, as disruptions in one part of the world had far-reaching effects on entire industries.

The concentration of supply chains in a few low-cost manufacturing hubs, particularly in Asia, made many U.S. industries vulnerable to regional disruptions. When COVID-19 shut down factories and ports in those regions, the lack of alternative suppliers or production hubs made it difficult for U.S. companies to pivot and find new sources of materials or components.[1523]

Many companies also adopted just-in-time inventory practices, minimizing their stockpiles to reduce costs. While this approach is efficient in stable conditions, it left businesses with little buffer when the pandemic disrupted supply chains. With inventory depleted and suppliers unable to deliver on time, many businesses were forced to halt operations. The National Association of Manufacturers found that more than 78 percent of manufacturers reported significant supply chain disruptions during the pandemic, with more than half citing just-in-time inventory as a contributing factor.[1524]

The inability to secure necessary inputs or products during the pandemic led to widespread business closures, especially for SMEs. The lack of diversified supply chains magnified the challenges businesses faced, as they struggled to cope with inventory shortages, rising costs, and production delays.

SMEs were particularly vulnerable to supply chain disruptions. Unlike large multinational corporations with diversified suppliers or the financial resources to weather the crisis, many SMEs had limited bargaining power and fewer options for securing alternative suppliers. SMEs accounted for nearly 60 percent of all business closures during the first year of the pandemic.[1525] A survey by Goldman Sachs found that 88 percent of small businesses in the U.S. reported supply chain disruptions, with more than 70 percent citing it as a major reason for their financial difficulties.[1526]

Supply chain disruptions hit the retail and manufacturing sectors particularly hard, leading to thousands of business closures. Retailers, already grappling with reduced consumer demand, faced additional challenges from inventory shortages. The National Retail Federation (NRF) reported that more than 8,700 retail stores closed in 2020, driven in part by supply chain disruptions that made it impossible to meet customer demand.[1527] The manufacturing sector also

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[1523] Xu Z, *et al., Impacts of COVID-19 on Global Supply Chains: Facts and Perspectives*, IEEE ENG'G MGMT. REV. (Aug. 24, 2020).
[1524] Press Release, Nat'l Associate of Manufactures, Manufacturers' Third Quarter Outlook Shows Continued Supply Chain Issues, Growing Workforce Needs and Rising Costs (Sept. 19, 2022).
[1525] David Dam*, et al., Many Small Businesses in the Services Sector Are Unlikely to Reopen*, FED. RESERVE BANK OF N.Y. (May 5, 2021).
[1526] *88% of Small Business Owners Say Inflation is Impacting Their Business, According to Bank of America Small Business Owners Report; Despite Concerns, 64% of Entrepreneurs Anticipate Revenue Growth and Business Expansion,* BANK OF AMERICA (May 3, 2022).
[1527] Melissa Minkow, *Over 8,700 store closures in 2021 – What retailers should consider to stay relevant,* THE SUPPLY CHAIN (Sept. 6, 2021).

saw significant closures, with the U.S. Census Bureau reporting that more nearly 65 percent of U.S. manufacturers reporting supply chain disruptions in mid-2021.[1528]

Supply chain disruptions also led to rising costs for raw materials and finished goods, further squeezing businesses' profit margins. By late 2021, prices for materials such as lumber, steel, and plastics had surged by 20-40 percent due to supply shortages, according to the Producer Price Index (PPI).[1529] Many businesses were unable to absorb these costs and passed them on to consumers, reducing demand and exacerbating the financial strain on companies already struggling with supply chain disruptions.

The failure to diversify supply chains before the pandemic not only extended the immediate economic damage but also increased long-term vulnerabilities for U.S. businesses. Even as the pandemic receded, supply chain disruptions continued to cause financial strain and business closures.

One of the most significant examples of persistent supply chain disruptions is the global semiconductor shortage, which continued to affect the automotive, electronics, and consumer goods sectors well into 2022 and 2023. The U.S. Department of Commerce estimated that the shortage cost the U.S. economy $240 billion in 2021 alone, with major automakers reporting billions in lost revenue due to reduced production.[1530] Without a diversified semiconductor supply chain, U.S. businesses remain vulnerable to future disruptions in chip production, especially as demand for semiconductors continues to rise with the growth of electric vehicles and 5G technologies.

In response to these challenges, policymakers and business leaders have called for greater supply chain diversification to mitigate future risks. However, rebuilding and diversifying supply chains is a long-term process, and many U.S. businesses continue to face vulnerabilities stemming from the lack of diversified supply networks.

The COVID-19 pandemic revealed the fragility of global supply chains and the dangers of overreliance on concentrated suppliers and regions. In the U.S., the lack of diversified supply chains exacerbated the economic impact of the pandemic, leading to widespread business closures, especially among small and medium-sized enterprises. Supply chain disruptions not only increased immediate economic vulnerability but also extended the long-term risks facing American businesses. To build resilience against future crises, it is essential for U.S. companies to invest in diversifying their supply chains, expanding domestic manufacturing capabilities, and reducing dependence on single sources of critical inputs.

[1528] Jane Callen, *Census Bureau's Small Business Pulse Survey Reveals Delays From Domestic, Foreign Suppliers*, U.S. CENSUS BUREAU (Aug. 9, 2021).
[1529] Ana Maria Santacreu & Jesse LaBelle, *Supply Chain Disruptions and Inflation During COVID-19,* FEDERAL RESERVE BANK OF ST. LOUIS (May 12, 2022).
[1530] Press Release, U.S. Dep't of Commerce, Analysis for CHIPS Act and BIA Briefing (Apr. 6, 2022).

II. The COVID-19 Pandemic's Impact on American Workers

The COVID-19 pandemic had a profound impact on the U.S. labor market. The rapid spread of the virus led to widespread lockdowns, social distancing measures, and a sudden halt in economic activity. As a result, unemployment rates in the U.S. surged to levels exceeding the 2007-09 Great Recession and not seen since the 1929-39 Great Depression.[1531]

The spike in unemployment during the pandemic was largely fueled by mass lockdowns and the subsequent abrupt closure of businesses across the country. Industries that rely heavily on physical interaction, such as hospitality, retail, and travel, were particularly hard hit. As state and local governments imposed lockdowns and social distancing measures to curb the spread of the virus, many businesses were forced to shut down or operate at significantly reduced capacity, leading to mass layoffs and furloughs.[1532]

Moreover, the uncertainty surrounding the duration of the pandemic and its economic impact led many businesses to implement hiring freezes and reduce their workforce as a precautionary measure. Furthermore, the supply chain disruptions caused by the global nature of the pandemic also contributed to job losses, particularly in manufacturing and other export-dependent industries.[1533]

Before analyzing unemployment during the pandemic in more detail, a brief discussion of Federal Government actions intended to alleviate unemployment is necessary.

In response to the unprecedented economic impacts of the pandemic, the U.S. government implemented a series of economic relief measures to support workers and businesses. The most significant of these was the $2.2 *trillion* CARES Act[1534] passed in March 2020 and was amended several times. The following provisions of the CARES Act have a nexus to alleviating unemployment.

<u>Three Provisions Enhancing Unemployment Benefits</u>[1535]

First, FPUC provided an additional $600 per week to individuals receiving unemployment benefits from March to July 2020.[1536] This was later reduced to $300 per week in subsequent extensions, provided the beneficiary's state agreed to certain conditions. Next, PUA provided benefits to those not typically eligible for regular unemployment, such as self-

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[1531] *See,* Rakesh Kochhar, *Unemployment rose higher in three months of COVID-19 than it did in two years of the Great Recession*, PEW RESEARCH CTR. (Jun. 11, 2020) (noting peak unemployment rate of 14.4% during the pandemic exceeded the peak unemployment of 10.6% during the Great Recession).
[1532] *COVID-19 ends longest employment recovery and expansion in CES history, causing unprecedented job losses in 2020,* U.S. BUREAU OF LAB. STAT. (June 2021).
[1533] Susan Helper & Evan Soltas, *Why the Pandemic Has Disrupted Supply Chains*, The White House (June 17, 2021).
[1534] Pub. L. No. 116-136, 134 Stat. 281 (2020) as amended through Pub. L. No. 118-47 (2024).
[1535] *See,* "Enhanced Unemployment".
[1536] Pub. L. No. 116-136, 134 Stat. 281 § 2104 (2020).

employed workers, freelancers, and gig workers.[1537] PEUC[1538] extended unemployment benefits 13 weeks beyond the usual duration for those who had exhausted regular state unemployment benefits.

Direct Payments to Households

The CARES Act also included direct stimulus payments to individuals and families, with most Americans receiving $1,200 per adult and $500 per child. These payments were intended to provide immediate relief to those affected by the pandemic and stimulate economic activity. First round (March 2020): the CARES Act provided $1,200 per eligible adult and $500 per child.[1539] Second round (December 2020): the Consolidated Appropriations Act (CAA), 2021 provided $600 per eligible adult and $600 per child.[1540] Third round (March 2021) the ARPA provided $1,400 per eligible adult and $1,400 per child.[1541] More than 475 *million* total payments were made through the CARES Act, CAA, and ARPA, and the total of these payments exceed $1.4 *trillion* dollars.[1542]

Paycheck Protection Program[1543]

PPP provided forgivable loans to small businesses to help them cover payroll costs and avoid layoffs. This program indirectly benefited employees since it was intended to assist the businesses that employed them. While the program was successful in preventing some job losses, it faced criticism for being poorly targeted and for delays in the distribution of funds. Some businesses, particularly those in lower income communities, struggled to access PPP loans due to complex eligibility criteria and bureaucratic hurdles. PPP was also the target of rampant fraud, waste, and abuse.

Employee Retention Credit [hereinafter "ERC"][1544]

[1537] *Id.*
[1538] *Id.*
[1539] *See, Id*. (Individuals earning less than $75,000 received a stimulus payment of $1,200; married couples earning less than $150,000 received a payment of $2,400; and households received an additional $500 for each dependent they claimed. The payments were reduced at higher levels of income and phased out entirely for households with incomes above $99,000 (for single filers without children) or $198,000 (for married couples without children).
[1540] Pub. L. No.116-260, 134 Stat. 1182, *et seq.* (2020). Eligibility criteria largely followed those for the earlier round of stimulus, with single households eligible for the full stimulus amount up to $75,000 in income ($150,000 for married households). The stimulus amount fell at higher income levels, with childless households with incomes up to $87,000 (or $174,000 if married filing jointly) receiving a payment.).
[1541] Pub. L. No.117-2, 135 Stat. 4, *et seq.* (2021). This plan continued to pay the full stimulus amount of $1,400 to households earning up to $150,000, but phased the payments out more rapidly beyond that threshold than initially proposed, so that households with incomes above $80,000 (for single filers without children) or $160,000 (for married couples without children) received no stimulus.
[1542] *Update: Three rounds of stimulus checks. See how many went out and for how much*, PANDEMIC OVERSIGHT, *available at* https://www.pandemicoversight.gov/data-interactive-tools/data-stories/update-three-rounds-stimulus-checks-see-how-many-went-out-and (Feb. 17, 2022) (citing Internal Revenue Service compiled data as of December 31, 2021).
[1543] Pub. L. No. 116-136, 134 Stat. 281 § 1102 (2020). For a more comprehensive discussion of PPP, see section ## above.
[1544] Pub. L. No. 116-136, 134 Stat. 281 § 2301 (2020).

ERC was a broad-based refundable tax credit designed to encourage employers to keep employees on their payroll. This program also indirectly benefited employees since it was intended to assist the businesses that employed them. The credit is 50 percent of up to $10,000 in wages paid by an employer whose business is fully or partially suspended because of COVID-19 or whose gross receipts decline by more than 50 percent.

Augmenting the Emergency Food Assistance Program [hereinafter "TEFAP"][1545]

The CARES Act provided an additional $450 million for TEFAP, a federally funded program that distributes food to food banks, food pantries, soup kitchens and other facilities serving low-income Americans.

Economic Injury Disaster Loans[1546]

Small businesses, including agricultural businesses and nonprofits, could apply for low-interest loans to help cover working capital and operating expenses. The EIDL program included an advance of up to $10,000 that did not need to be repaid, even if the loan application was denied. Again, this did not directly benefit unemployed persons but could indirectly benefit them if EIDL facilitated their employer staying in business.

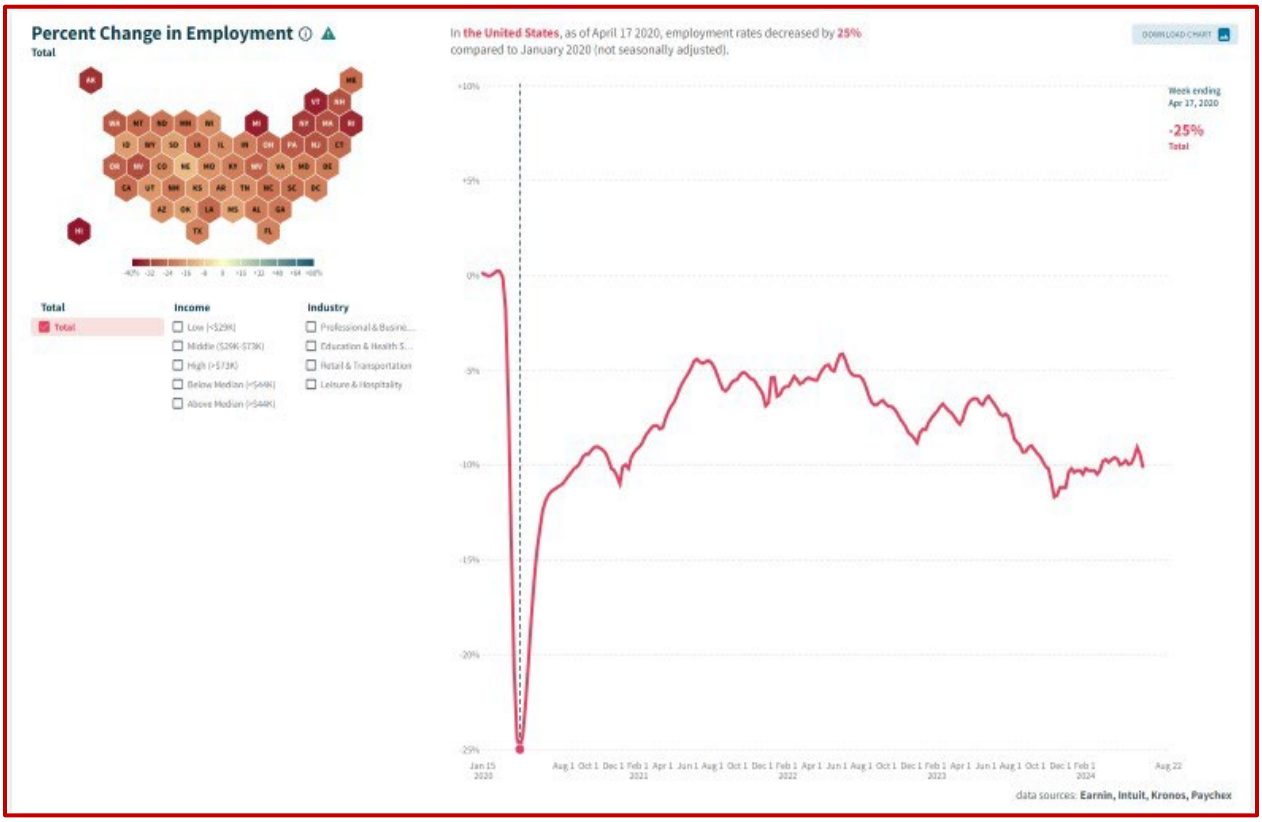
FINDING:	Public Health Officials' Arbitrary and Overly Broad Mitigation Measures and Aggressive Efforts to Squash Legitimate Scientific Debate Unnecessarily Exacerbated Unemployment.

Public health officials advised all Americans to socially distance six feet away from others, in addition to masking, as vital protective measures essential to curbing the pandemic. Furthermore, then-NIAID Director, White House Coronavirus Tak Force member, and the country's face of the pandemic, Dr. Fauci, made the decision to recommend that the President "shut the country down."[1547] Most states quickly operationalized this advice and mandated stay at home orders. At some point between March to June 2020, 38 states and Washington, D.C. mandated lockdowns, shelter in place, or other similar orders for all persons.[1548] Two states mandated stay at home measures for persons at risk.[1549] Six issued advisory guidance, and five states did not issue any orders or guidance.[1550]

In 2024, numerous senior public health officials that promoted social distancing admit that it lacked a scientific basis. As has been previously discussed in this report, Dr. Fauci and other senior U.S. public health officials advised Americans to socially distance six feet apart.[1551] For example, Dr. Fauci admitted that six-foot social distancing is not supported by an underlying

[1545] Pub. L. No. 116-136, 134 Stat. 281 § 11001 (2020).
[1546] Pub. L. No. 116-136, 134 Stat. 281 § 1101 (2020).
[1547] Aristos Georgiou, *Fauci Says He Told Trump to 'Shut the Country Down'*, NEWSWEEK (OCT. 7, 2020).
[1548] Amanda Moreland*, et al., Timing of State and Territorial COVID-19 Stay-at-Home Orders and Changes in Population Movement – United States, March 1-May 31, 2020*, MMWR (Sept. 4, 2020).
[1549] *Id.*
[1550] *Id.*
[1551] Kevin B. O'Reilly, *Dr. Fauci outlines 5 ways to blunt COVID-19 pandemic's resurgence*, JAMA (Aug. 4, 2020).

scientific study and "sort of just appeared."[1552] Further, Dr. Collins, testified that he was "not involved in that conversation" at the time and "did not see evidence" at the time, nor since, that supported six-foot social distancing.[1553]



While public health officials and other medical professionals are trained to be conservative in their recommendations and reduce health risk as much as possible, this unsupported advice—stay at home orders and maintaining six feet of distance, which states promptly implemented as mandates, had severe adverse impacts across society. Relevant to the discussion here, this advice significantly exacerbated business closures and unemployment.

At its peak, total employment rates across all industries decreased by 25 percent in mid-April 2020 from January 2020 levels and *remained well below that level for two years*.

While all unemployment cannot be attributed to social distancing and stay at home orders, statistics do show it played a considerable role. According to the U.S. Bureau of Labor Statistics, during 2020, 80 percent of businesses that were subjected to mandatory government mitigation measures told employees not to work or reduced hours compared to 54 percent of businesses that were not subjected to government-mandated mitigation measures.[1554] Finally, according to the Small Business Pulse Survey conducted by the U.S. Census Bureau, 31 percent

[1552] Fauci TI 2, *supra* note 81, at 183-184.
[1553] Collins TI, *supra* note 219, at 224.
[1554] U.S. BUREAU OF LAB. STAT., RESULTS OF THE 2020 BUSINESS RESPONSE SURVEY (2020).

of small businesses reported that social distancing measures significantly reduced their revenue in 2020, leading many to furlough or lay off workers.[1555]

Social distancing not only restricted business operations but also led to a significant reduction in consumer demand, which also added to unemployment. The fear of contracting the virus, combined with government mandates, led consumers to avoid engaging in normal economic activity. The U.S. Bureau of Economic Analysis [hereinafter "BEA"] reported a sharp decline in consumer spending during the early months of the pandemic, with a 6.7 percent decrease in March 2020 and a record 13.2 percent drop in April 2020.[1556] For context, the BEA has collected consumer spending data since 1959 and prior to the pandemic the worst monthly decline 2.5 percent in early 1987.[1557] This decline was driven by reduced spending on services, particularly in the sectors most affected by social distancing.

Public health officials not only made recommendations not supported by science which had devastating impacts on employment and the overall economy, they also doubled down on these decisions. For example, Dr. Collins' reaction to the Great Barrington Declaration.

The Great Barrington Declaration, published in October 2020, proposed an alternative strategy to the widespread social distancing, lockdowns, and restrictions implemented during the COVID-19 pandemic.[1558] The primary argument is that protecting the vulnerable while allowing others to maintain normal activities would minimize the economic fallout of the pandemic. By keeping businesses open, maintaining consumer demand, and avoiding large-scale layoffs, the economy might have avoided the severe contractions experienced in 2020.

The Great Barrington Declaration was one of the first publications that challenged the scientific basis of a "one size fits all" approach to social distancing and lockdowns. Dr. Collins called for a "quick and devastating published takedown of [the paper's] premises."[1559]

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[1555] Jane Callen, *Weekly Census Bureau Survey Provides Near-Real-Time Info on Businesses*, U.S. CENSUS BUREAU (May 14, 2020).
[1556] Emily Wavering Corcoran & Sonya Ravindranath Waddell, *Income, Consumption, and the COVID-19 Pandemic*, FED. RESERVE OF RICHMOND (June 18, 2020).
[1557] *Id.*
[1558] THE GREAT BARRINGTON DECLARATION, *supra* note 1281.
[1559] E-Mail from Francis Collins, M.D., Ph.D., Dir. Nat'l Insts. of Health, to Anthony Fauci, M.D., Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, *et al.* (Oct. 8, 2020, 2:31 PM).

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Thursday, October 8, 2020 2:31 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E]
(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: Great Barrington Declaration

Hi Tony and Cliff,

See https://gbdeclaration.org/ This proposal from the three fringe epidemiologists who met with the Secretary seems to be getting a lot of attention – and even a co-signature from Nobel Prize winner Mike Leavitt at Stanford. There needs to be a quick and devastating published take down of its premises. I don't see anything like that on line yet – is it underway?

Francis

Dr. Collins testified that he Great Barrington Declaration was a "dangerous approach", and he was "looking for a response from credible experts to get that response out there quickly before this becomes somehow a U.S. policy…"[1560]

Had legitimate scientific debate been allowed to occur, alternative courses of action, such as those proposed in the Great Barrington Declaration, may have been attempted with improved impacts of employment and the economy. In 2023 at a Braver Angels panel, Dr. Collins acknowledged that, during the pandemic, public health officials never really considered the downstream impacts of aggressive public health policy and that was a mistake:

> The public health people — we talked about this earlier and this really important point — if you're a public health person and you're trying to make a decision, you have this very narrow view of what the right decision is. And that is something that will save a life; it doesn't matter what else happens. So you attach infinite value to stopping the disease and saving a life. You attach zero value to whether this actually totally disrupts people's lives, ruins the economy, and has many kids kept out of school in a way that they never quite recover from. So, yeah, collateral damage. This is a public health mindset and I think a lot of us involved in trying to make those recommendations had that mindset ***and that was really unfortunate. It's another mistake we made.***[1561]

Social distancing measures had significant economic consequences that exacerbated unemployment and accelerated business closures. The data demonstrates that the reduction in consumer demand, operational restrictions, and the long-term economic ripple effects of social distancing contributed to one of the most severe economic downturns in recent history. As such, while public health considerations were paramount, the economic costs of social distancing underscore the need for a balanced approach that supports both health and economics. In other

[1560] Collins TI, *supra* note 219, at 242.
[1561] Wesley J. Smith, Francis Collins Disappointed as Public-Health Leader, NATIONAL REVIEW (Dec. 30, 2023) (emphasis added).

words, a more diverse voices from different disciplines (e.g., economists, industry leaders, educators) should have been part of the discussion to ensure downstream effects of these policies could be fully considered.

FINDING:	Pandemic Unemployment Disproportionately Impacted Sectors with Lower Wage Earners Compared to Higher Wage Earners, Such as Those in Professional Services, and Lower Wage Earners Continue to Remain Unemployed at Higher Rates and Will Likely Remain So Over the Next Decade.

It is not surprising that industries that necessarily involve close contact and face-to-face interaction, suffered worse unemployment than industries that could effectively function without close contact. For example, 70 percent of establishments in arts, entertainment, and recreation, and food services told employees not to work at some point during the pandemic in 2020.[1562]

In the figure below, the professional and business industry saw a brief 10 percent dip in employment rates in the earliest days of the pandemic, while leisure and hospitality experienced a nearly 60 percent plunge. Many professionals, particularly those in high-paying sectors like technology, finance, and consulting, were able to transition to remote work with relative ease.[1563] This allowed them to maintain employment and income levels despite the economic downturn caused by the pandemic. Lower-wage workers, especially those in service sectors such as hospitality, retail, and food services, were and remain unable to telework and faced much higher rates of job loss. These sectors were heavily affected by lockdowns and social distancing measures, leading to widespread layoffs and reduced working hours.[1564]

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[1562] U.S. BUREAU OF LAB. STAT., RESULTS OF THE 2020 BUSINESS RESPONSE SURVEY (2020).
[1563] *Id.* (Industries with the highest percentages of telework options in 2020 included educational services (60%), finance and insurance (58%), and corporate management (54%).).
[1564] *Id.* (Industries with largest percentage not offering telework in 2020 included accommodation and food service (91%), agriculture, forestry, fishing, and hunting (86%), and retail trade (75%).).

Percent Change in Employment
Retail & Transportation
In the United States, as of June 21 2024, employment rates in retail and transportation decreased by 9.8% compared to January 2020 (not seasonally adjusted).
Week ending Jun 21, 2024
+2.9%
Professional & Business Services
-9.8%
Retail & Transportation
-22.2%
Leisure & Hospitality
Total
Income
Industry
data sources: Earnin, Intuit, Kronos, Paychex

What is surprising, however, is, that as of June 2024, retail and transportation and leisure and hospitality employment rates are still well under pre-pandemic levels—more than 20 percent lower in the case of leisure and hospitality. A vast majority of retail, transportation, leisure, and hospitality employees are lower wage earners, which is reflected in the figure below showing that low wage earner employment rates remain 10 percent below pre-pandemic rates.

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Why haven't lower wage earners' employment rates recovered? The answer is likely that the conditions of the pandemic, specifically social distancing and lockdowns, greatly accelerated trends that were emerging before the pandemic, specifically remote work, e-commerce, and automation.[1565]

While remote work was already occurring prior to 2020 for many high wage earners, the pandemic pushed the rapid development of tools to improve teleworking, such as teleconferencing (e.g., Microsoft TEAMS, Zoom, etc.), document sharing tools, and cloud-based computing capacity.[1566] Remote work continues. In December 2023, nearly 35 percent of management and professionals reported teleworking at least one day a week.[1567] Service industry workers, who are predominately lower wage earners, only report 4 percent remote work.[1568]

E-commerce grew at five times faster than before the pandemic and "[o]ther kinds of virtual transactions such as telemedicine, online banking, and streaming entertainment have also taken off."[1569] This trend has only increased in the years following the pandemic, making many retail and administrative support jobs obsolete.

[1565] Susan Lund, *et al., The future of work after COVID-19,* at 5, MCKINSEY GLOBAL INST. (Feb. 18, 2021).
[1566] *Id.*
[1567] *About 1 in 3 workers in management, professionals, and related occupations teleworked, November 2023*, U.S. BUREAU OF LABOR STATISTICS (Dec. 19, 2023).
[1568] *Id.*
[1569] Susan Lund, *et al., The future of work after COVID-19,* at 10, MCKINSEY GLOBAL INST. (Feb. 18, 2021).

The pandemic caused rapid development of automation and artificial intelligence [hereinafter "AI"].[1570] The common feature of pandemic-driven automation technology is their correlation to replacing human interaction and physical proximity.[1571] Two-thirds of executives surveyed stated they intend to increase investment in automation and AI,[1572] which will predominately take the place of lower-wage workers.

Prior to the pandemic and with relative ease, a lower wage-earning employee could move from retail and service entry to an entry-level data entry position with little or no additional skills, education, and training required. The trends discussed above make such a transition unlikely because the opportunities will very likely not be there. By 2030, up to 25 percent of all U.S. workers could need to shift to other occupations that require greater training, education, and skills than they currently possess.[1573]

[1570] *Id.*
[1571] *Id.*
[1572] *Id.* at 11.
[1573] *Id.* at 16.

III. The Federal Reserve's Efforts to Mitigate the Economic Impacts of the COVID-19 Pandemic

The Federal Reserve took several actions to mitigate the economic impacts of the COVID-19 pandemic.

The Federal Reserve System and its Functions

In 1913 Congress passed the Federal Reserve Act[1574] with the purpose of creating "a safer, more flexible, and more stable monetary and financial system."[1575] in which they rejected having one central national bank.[1576] Instead, Congress opted for a three-feature Federal Reserve System composed of three bodies: a central governing body of the Board of Governors, "a decentralized operating structure" of the 12 Reserve Banks, and the FOMC consisting of all members of the Board of Governors and the presidents of all the Reserve Banks.[1577]

Congress provides oversight of the Board of Governors,[1578] whose seven members are appointed by the President of the U.S. with the advice and consent of the Senate.[1579] The Federal Reserve System, however, operates largely independent from the legislative and executive branches of government.[1580]

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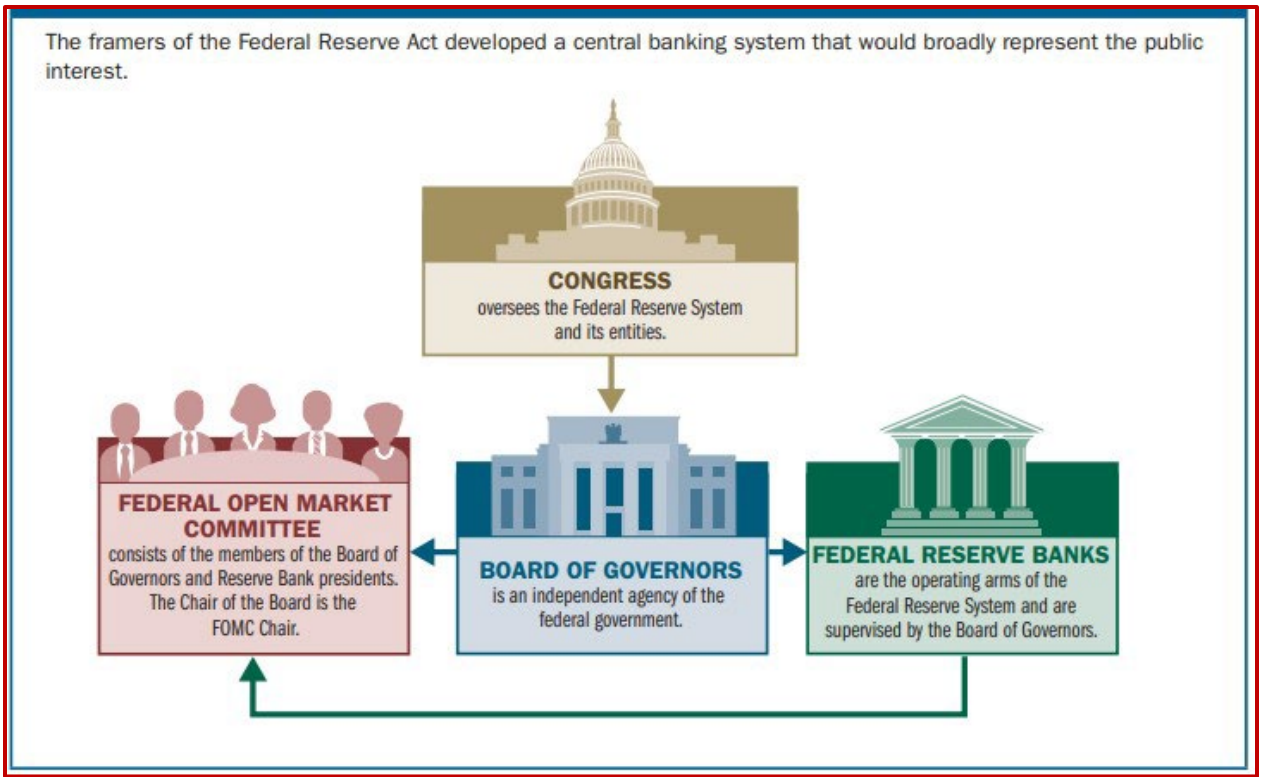
[1574] 12 U.S.C. § 221 *et seq.*
[1575] U.S. FED. RSRV. SYS., PUB. EDUC. & OUTREACH, THE FED EXPLAINED: WHAT THE CENTRAL BANK DOES, at 21 (2021).
[1576] *Id.* at 2.
[1577] *Id.*
[1578] 12 U.S.C. § 225b.
[1579] 12 U.S.C. § 241.
[1580] *See* MARC LABONTE, CONG. RESEARCH. SERVS., IF0054, INTRODUCTION TO FINANCIAL SERVICES: THE FEDERAL RESERVE 2 (2023) ("Economists have justified the Fed's independence on the grounds that monetary policy decisions that are insulated from short-term political pressures result in better economic outcomes.").


The framers of the Federal Reserve Act developed a central banking system that would broadly represent the public interest.
CONGRESS
oversees the Federal Reserve System and its entities.
FEDERAL OPEN MARKET COMMITTEE
consists of the members of the Board of Governors and Reserve Bank presidents. The Chair of the Board is the FOMC Chair.
BOARD OF GOVERNORS
is an independent agency of the federal government.
FEDERAL RESERVE BANKS
are the operating arms of the Federal Reserve System and are supervised by the Board of Governors.

The Federal Reserve System executes five core functions in the public interest. The functions relevant to the COVID-19 pandemic are:

Conducting the Nation's Monetary Policy

In a 1977 amendment to the Federal Reserve Act, Congress updated the Federal Reserve's mandate, namely for the two decision-making bodies, the Board of Governors and the FOMC, to specifically promote the goals of "maximum employment, stable prices, and moderate long-term interest rates."[1581] The primary monetary policy tool the Federal Reserve uses to implement its mandate is the federal funds rate, which is often referred to as the overnight bank lending rate.[1582] The Federal Reserve makes policy decisions to adjust this rate to manage financial conditions, reducing interest rates to stimulate economic activity during economic downturns and increasing interest rates to cool an overheating economy and curb inflation.

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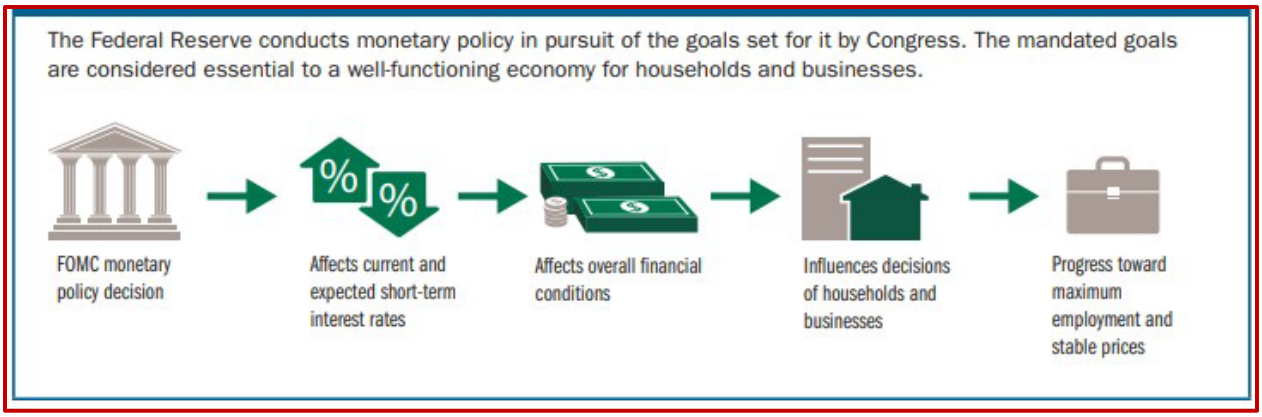
[1581] 12 U.S.C. § 225a.
[1582] MARC LABONTE, CONG. RSCH. SERVS., *supra* note 1580.


The Federal Reserve conducts monetary policy in pursuit of the goals set for it by Congress. The mandated goals are considered essential to a well-functioning economy for households and businesses.
FOMC monetary policy decision
Affects current and expected short-term interest rates
Affects overall financial conditions
Influences decisions of households and businesses
Progress toward maximum employment and stable prices

In addition to adjusting the federal funds rate, the Federal Reserve uses open market operations as a tool to implement monetary policy.[1583] This occurs when the FOMC directs the Open Market Desk at the Federal Reserve Bank of New York to permanently or temporarily buy or sell government securities in the open market to influence the supply of money by increasing or decreasing reserves in the banking system, respectively.[1584] These operations also help control short-term interest rates and the amount of money in circulation.

Beyond adjusting the short-term interest rates and open market operations, the Federal Reserve will use quantitative easing [hereinafter "QE"] as a monetary policy tool to stimulate the economy when traditional methods, such as lowering short-term interest rates, become ineffective—usually during periods of very low or near-zero interest rates.[1585] QE involves the large-scale purchase of financial assets by the Federal Reserve, particularly government securities like U.S. Treasury bonds, as well as mortgage-backed securities [hereinafter "MBS"]. The goal is to inject liquidity into the economy, lower long-term interest rates, and encourage lending and investment.[1586] When the Federal Reserve, purchases large quantities of government and mortgage-backed securities from banks and other financial institutions, it increases the demand for these securities, which in turn raises their prices and lowers their yields (interest rates). QE sends a powerful message to financial markets that the Federal Reserve is committed to support the economy, which also boosts confidence among investors, businesses, and consumers.[1587]

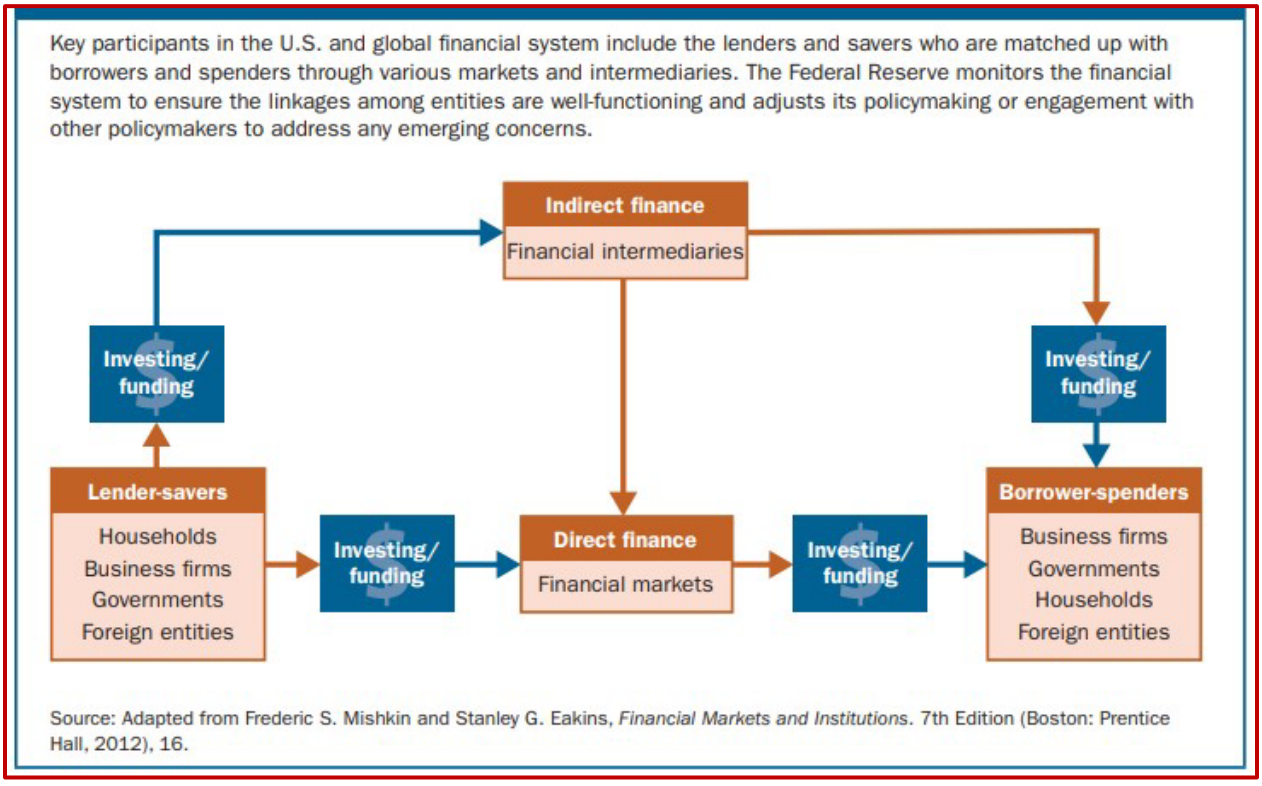
Finally, the Federal Reserve also uses a tool referred to as 'forward guidance" to conduct monetary policy. Forward guidance is a communication tool used by central banks, including the Federal Reserve, to provide information to the public and financial markets about the future path of monetary policy, particularly interest rates.[1588] The goal of forward guidance is to influence expectations and behavior by giving clear indications of what the central bank plans to do in the future, which can help stabilize the economy and achieve policy objectives like price stability

[1583] U.S. FED. RSRV. SYS., PUB. EDUC. & OUTREACH, THE FED EXPLAINED: WHAT THE CENTRAL BANK DOES (2021), at 36.
[1584] *Id.*
[1585] Anna-Louise Jackson, *Quantitative Easing Explained*, at 1 FORBES (Feb. 13, 2024).
[1586] *Id.*
[1587] *Id.*
[1588] PUB. EDUC. & OUTREACH, THE FED EXPLAINED: WHAT THE CENTRAL BANK DOES, U.S. FED. RSRV. SYS., at 32 (2021).

and full employment.[1589] During economic crises, such as the 2008 financial crisis or the COVID-19 pandemic, the Fed has used forward guidance to reassure markets and the public that it would maintain accommodative policies (e.g., low interest rates) to support economic recovery.

Maintaining Stability of the Financial System

"A financial system is considered stable when financial institutions—banks, savings and loans, and other financial product and service providers—and financial markets are able to provide households, communities, and businesses with the resources, services, and products they need to invest, grow, and participate in a well-functioning economy."[1590] In other words, a stable financial system effectively links individual and institutional savers and lenders with borrowers and spenders.


Key participants in the U.S. and global financial system include the lenders and savers who are matched up with borrowers and spenders through various markets and intermediaries. The Federal Reserve monitors the financial system to ensure the linkages among entities are well-functioning and adjusts its policymaking or engagement with other policymakers to address any emerging concerns.
Indirect finance
Financial intermediaries
Investing/ funding
Investing/ funding
Lender-savers
Households
Business firms
Governments
Foreign entities
Investing/ funding
Direct finance
Financial markets
Investing/ funding
Borrower-spenders
Business firms
Governments
Households
Foreign entities
Source: Adapted from Frederic S. Mishkin and Stanley G. Eakins, Financial Markets and Institutions. 7th Edition (Boston: Prentice Hall, 2012), 16.

The Federal Reserve monitors the financial system for signs of instability, such as excessive risk-taking, asset bubbles, or emerging vulnerabilities.[1591] By identifying and addressing potential threats early, the Federal Reserve can take preventive measures to avert financial crises.

[1589] U.S. FED. RSRV. SYS., PUB. EDUC. & OUTREACH, THE FED EXPLAINED: WHAT THE CENTRAL BANK DOES (2021), AT 32.
[1590] *Id.*
[1591] *Id.* at 50.

By providing emergency liquidity to financial institutions facing short-term funding problems, the Federal Reserve helps maintain confidence in the financial system and prevents the failure of institutions that are *otherwise solvent*.[1592] The main mechanism through which the Federal Reserve acts as a lender of last resort is the discount window.[1593] Banks and other eligible financial institutions can borrow money from the Federal Reserve's discount window when they cannot obtain sufficient liquidity from other sources, such as the interbank lending market.[1594] These loans are typically short-term and are collateralized by high-quality assets held by the borrowing institution.[1595]

In times of "unusual or exigent circumstances," the Federal Reserve is authorized to provide liquidity *to non-depository institutions* under section 13(3) of the Federal Reserve Act.[1596] A primary way in which the Federal Reserve operationalizes this authority is the creation of *lending facilities* to support overall market liquidity. It is rare for the Federal Reserve to use this authority, but it did use it during the 2007–09 financial crisis and COVID-19 pandemic to prevent harm to the U.S. economy.[1597] Under amendments enacted under the Dodd-Frank Act, emergency lending programs under section 13(3) of the Federal Reserve Act must be broad-based and not designed to support a single institution, among other requirements.[1598] In addition, Congress requires that the Federal Reserve ensure that taxpayers are protected against losses through not bailout insolvent institutions and collateral requirements.[1599] Consistent with this, actions taken under section 13(3) authority are taken with the approval of the Secretary of the U.S. Department of Treasury.[1600] The Dodd-Frank Act amendments allow the Federal Reserve to disclose details of emergency lending programs, including the names of borrowers, the amounts borrowed, and the terms of the loans to Congress.[1601] This transparency is intended to increase public accountability for the Federal Reserve's emergency actions.

Supervising and Regulating Financial Institutions

The Federal Reserve supervises and regulates banks to ensure they operate safely and soundly. This involves regular examinations, monitoring financial conditions, and enforcing regulatory requirements to mitigate risks that could threaten the stability of the financial system.

[1592] *See,* MARC LABONTE, CONG. RESEARCH SERVS. R44185, FEDERAL RESERVE: EMERGENCY LENDING 15 (2020) (noting that the Federal Reserve is not authorized to act as a lender of last resort to *insolvent* firms and discussing the debate of whether the four "too big to fail" banks were actually insolvent at the time of the Federal Reserve's intervention during the 2007-09 financial crisis).
[1593] *Id.*
[1594] *The Discount Window*, THE FED. RSRV. DISC. WINDOW PAYMENT SYS. RISK, *available at* https://www.frbdiscountwindow.org/Pages/General-Information/The-Discount-Window#:~:text=Most%20performing%20or%20investment%20grade,to%20secure%20Discount%20Window%20loans (June 7, 2024).
[1595] *Id.*
[1596] 12 U.S.C. § 343(3)(A).
[1597] MARC LABONTE, *supra* note 1592.
[1598] 12 U.S.C. § 343(3)(A).
[1599] 12 U.S.C. § 343(3)(B)(ii).
[1600] 12 U.S.C. § 343(3)(B)(iv).
[1601] 12 U.S.C. § 343(3)(C).

Most notably, the Federal Reserve conducts stress tests on large financial institutions to assess their ability to withstand severe economic shocks. These tests help ensure that banks have adequate capital to continue lending during crises. These stress tests are mandated by the Dodd-Frank-Act, enacted in response to the 2008 financial crisis. The Federal Reserve engages in other supervisory and regulatory activities, but further explanation of those activities is not necessary to assess the Federal Reserve's actions in response to the pandemic.

Summary of Federal Reserve's Major Actions During the Pandemic

The Federal Reserve's aggressive and unprecedented response to the COVID-19 pandemic involved using all monetary policy tools available to it. These actions were essential in preventing a more severe economic downturn, though they also may have set new precedents for the Federal Reserve's role in future crises.

January – February 2020: Early Monitoring and Initial Posture

January 2020: The Federal Reserve began monitoring the emerging COVID-19 outbreak, assessing potential risks to the U.S. economy. During this period, it maintained its monetary policy stance, with no immediate changes to interest rates.[1602]

February 28, 2020: In response to increasing concerns about the economic impact of COVID-19, Chair Jerome Powell issued a statement indicating that the central bank was prepared to "use our tools and act as appropriate to support the economy."[1603]

March 2020: Federal Reserve takes Several Monetary Policy Actions

March 3, 2020: The Federal Reserve made an emergency 50 basis point cut to the federal funds rate, lowering it to a range of 1.00 percent to 1.25 percent. This marked the first emergency rate cut since the 2008 financial crisis and was aimed at addressing the growing economic risks from the pandemic.[1604]

March 15, 2020: The Federal Reserve made another emergency rate cut, this time by 100 basis points, bringing the federal funds rate down to a range of 0 percent to 0.25 percent. This move effectively returned rates to the near-zero levels seen during the financial crisis. The Federal Reserve also launched a new round of QE, pledging to purchase at least $700 billion in Treasury securities and MBS.[1605]

[1602] Press Release, The Fed. Rsrv., Meeting, January 28-29, 2020 (Jan. 29, 2020).
[1603] Press Release, The Fed. Rsrv., Statement from Federal Reserve Chair Jerome H. Powell, February 28, 2020 (Feb. 28, 2020).
[1604] Press Release, The Fed. Rsrv., Meeting, March 3, 2020 (Mar. 3, 2020).
[1605] Press Release, The Fed. Rsrv., Meeting, March 15, 2020 (Unscheduled) (Mar. 15, 2020).

March 17, 2020: The Federal Reserve established the Commercial Paper Funding Facility [hereinafter "CPFF"] to support the flow of credit to households and businesses by providing liquidity to the commercial paper market.[1606]

March 18, 2020: The Federal Reserve created the Money Market Mutual Fund Liquidity Facility [hereinafter "MMLF"] to enhance the liquidity and functioning of money markets, ensuring that money market mutual funds could meet investor redemption demands.[1607]

March 23, 2020: The Federal Reserve announced extensive measures to support the economy, including open-ended purchases of Treasury securities and MBS (essentially unlimited QE). Additionally, it introduced several new facilities:

- Primary Market Corporate Credit Facility: To support corporate bond issuance.
- Secondary Market Corporate Credit Facility [hereinafter "SMCCF"]: To support trading in corporate bonds.
- Term Asset-Backed Securities Loan Facility: To support the issuance of asset-backed securities.
- Expanded CPFF and MMLF: To provide further liquidity to financial markets.[1608]

<u>April 2020: Support to Small Businesses and Municipalities</u>

April 6, 2020: The Federal Reserve announced the Paycheck Protection Program Liquidity Facility to support the SBA's PPP by providing liquidity to participating financial institutions.[1609]

April 9, 2020: The Federal Reserve further expanded its interventions, introducing the Main Street Lending Program to provide up to $600 billion in loans to small and medium-sized businesses. It also established the Municipal Liquidity Facility to purchase short-term debt directly from state and local governments, providing them with essential liquidity.[1610]

[1606] Press Release, The Fed. Rsrv., Federal Reserve Board Announces Establishment of a Commercial Paper Funding Facility (CPFF) to Support the Flow of Credit to Households and Businesses, March 17, 2020 (Mar. 17, 2020).
[1607] Press Release, The Fed. Rsrv., Federal Reserve Board Broadens Program of Support for the Flow of Credit to Households and Businesses by Establishing a Money Market Mutual Fund Liquidity Facility (MMLF), March 18, 2020 (Mar. 18, 2020).
[1608] Press Release, The Fed. Rsrv., Federal Reserve Announces Extensive New Measures to Support the Economy, March 23, 2020 (Mar. 23, 2020).
[1609] Press Release, The Fed. Rsrv., Federal Reserve will Establish a Facility to Facilitate Lending to Small Businesses Via the Small Business Administration's Paycheck Protection Program (PPP) by Providing Term Financing Backed by PPP Loans, April 6, 2020 (Apr. 6, 2020).
[1610] Press Release, The Fed. Rsrv., Federal Reserve Takes Additional Actions to Provide up to $2.3 Trillion in Loans to Support the Economy, April 9, 2020 (Apr. 9, 2020).

May - June 2020: Implementation and Adjustments

May 12, 2020: The Federal Reserve began purchasing corporate bond exchange-traded funds through the SMCCF, marking the first time it had intervened in the corporate bond market in this manner.[1611]

June 8, 2020: The Federal Reserve expanded the Main Street Lending Program to allow more businesses to qualify for support by adjusting loan terms and eligibility criteria.[1612]

July - August 2020: Continued Support and Policy Adjustments

July 29, 2020: The FOMC reaffirmed its commitment to using its full range of tools to support the U.S. economy, maintaining the federal funds rate at 0 percent to 0.25 percent and continuing its asset purchases.[1613]

August 27, 2020: The Federal Reserve amended its policy framework under its "Statement on Longer-Run Goals and Monetary Policy Strategy," adopting a flexible form of average inflation targeting. This allowed inflation to run moderately above 2 percent for some time to make up for periods when it had been below that target.[1614]

September - December 2020: Ongoing Adjustments and New Measures

September 16, 2020: The Federal Reserve reiterated its commitment to maintaining accommodative monetary policy, signaling that rates would remain near zero until labor market conditions had reached levels consistent with the FOMC's assessments of maximum employment and inflation had risen to 2 percent and was on track to moderately exceed that rate for some time.[1615]

December 16, 2020: The Federal Reserve announced that it would continue purchasing at least $120 billion of Treasury securities and agency mortgage-backed securities per month until substantial further progress had been made toward the Committee’s goals of maximum employment and price stability.[1616]

[1611] Press Release, The Fed. Rsrv., Federal Reserve Publishes Updates to the Term Sheet for the Term Asset-Backed Securities Loan Facility (TALF) and Announces Information to be Disclosed Monthly for the TALF and the Paycheck Protection Program Liquidity Facility, May 12, 2020 (May 12, 2020).
[1612] Press Release, The Fed. Rsrv., Federal Reserve Board Expands Its Main Street Lending Program to Allow More Small and Medium-Sized Businesses to be Able to Receive Support, June 8, 2020 (Jun. 8, 2020).
[1613] Press Release, The Fed. Rsrv., Federal Reserve Board Announces an Extension Through December 31 of Its Lending Facilities That Were Scheduled to Expire on or Around September 30, July 28, 2020 (Jul. 29, 2020).
[1614] Statement on Longer-Run Goals and Monetary Policy Strategy, Board of Governors of the Fed. Rsrv. System (Adopted effective Jan. 24, 2012, reaffirmed effective Jan. 30, 2024).
[1615] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Sep. 16, 2020).
[1616] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Dec. 16, 2020).

January - March 2021: Transition and Sustained Support

January 27, 2021: The Federal Reserve maintained its accommodative stance, keeping interest rates near zero and continuing its asset purchase program, emphasizing that the economic recovery was still uneven and far from complete.[1617]

March 17, 2021: The Federal Reserve reiterated its commitment to supporting the economy, signaling that it would not raise interest rates until 2023 at the earliest, and that asset purchases would continue until substantial progress was made.[1618]

April - December 2021: Preparing for Policy Normalization

April 28, 2021: The Federal Reserve maintained its policy stance but began discussing the potential for tapering asset purchases as the economy showed signs of recovery.[1619]

June 16, 2021: The Federal Reserve indicated it might begin to taper asset purchases sooner than previously anticipated, acknowledging that inflation was running higher than expected.[1620]

November 3, 2021: The Federal Reserve announced it would begin tapering its asset purchases, reducing the pace of its monthly bond-buying by $15 billion each month, with the goal of ending the program by mid-2022.[1621]

December 15, 2021: The Federal Reserve accelerated its tapering process, doubling the pace of asset purchase reductions to $30 billion per month, and signaled that interest rate hikes could begin in 2022 in response to rising inflation.[1622]

January - March 2022: Transition to Policy Tightening

March 16, 2022: The Federal Reserve raised interest rates by 25 basis points, marking its first-rate hike since 2018, and signaled a series of rate increases to combat inflation and begin the process of normalizing monetary policy.[1623]

FINDING: The Federal Reserve's Aggressive, Early Actions Blunted Economic Damage of the Pandemic but Contributed to Staggering Inflation in Late 2021 Through 2022.

[1617] Press Release, The Fed. Rsrv., Implementation Note issued January 27, 2021(Jan. 27, 2021).
[1618] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Mar. 17, 2021).
[1619] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Apr. 28, 2021).
[1620] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Jun. 16, 2021).
[1621] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Nov. 3, 2021).
[1622] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Dec. 15, 2021).
[1623] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Mar. 16, 2022).

Within two weeks of COVID-19 being declared a pandemic, the Federal Reserve threw every tool at its disposal to blunt the economic impact of the pandemic. The Fed quickly slashed the federal funds rate to near zero to increase liquidity and cushion the economic impact of the pandemic.[1624] The Federal Reserve embarked on an aggressive QE program, initially purchasing large $500 billion U.S. Treasury and $200 billion mortgage-backed securities to provide liquidity to the financial system.[1625] And under its Federal Reserve Act section 13(3) authority, the Federal Reserve revived or stood up the first few of what would become many emergency lending facilities to support businesses, municipalities, and financial markets.[1626]

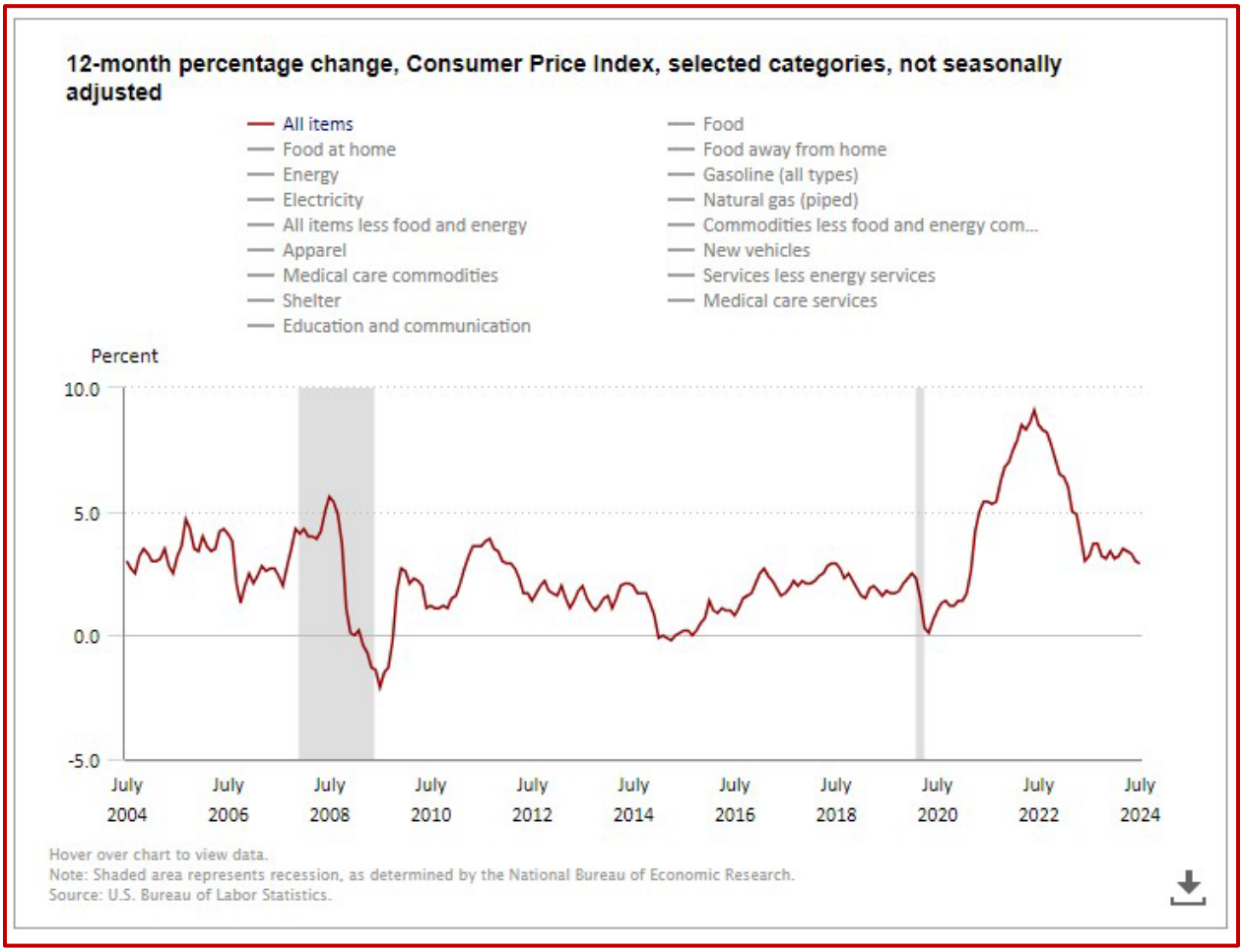
These actions helped stabilize financial markets, preventing a deeper financial crisis. The Federal Reserve's measures, combined with fiscal stimulus measures passed by Congress, provided critical support to businesses and households, mitigating the economic downturn.

The Federal Reserve's actions, along with substantial government spending, helped the economy recover more rapidly than many expected. By late 2020 and into 2021, economic growth had rebounded strongly, with Gross Domestic Product growth rates returning to positive territory.[1627] Without the Federal Reserve's aggressive intervention, the economic damage from the pandemic could have been much more severe and prolonged, potentially leading to a deeper and longer-lasting recession.[1628]

However, the combination of the aggressive monetary policy and fiscal stimulus fueled a surge in demand as businesses reopened and consumers spent their savings and stimulus checks. Global supply chains were already strained due to the pandemic, and the surge in demand exacerbated these issues, leading to higher prices for goods and services. For example, U.S. auto production decreased from 11.7 million vehicles in July 2020, close to the pre-pandemic rate, to fewer than 9 million in late 2021.[1629] With interest rates at historic lows and stimulus money injected into the economy, there was considerable consumer demand for automobiles, but prolonged shortages of chips and other key components restrained production and increased prices.[1630] The tight labor market, with employers struggling to fill positions, also contributed to wage growth and further inflationary pressures.[1631]

[1624] Press Release, The Fed. Rsrv., Meeting, March 15, 2020 (Unscheduled) (Mar. 15, 2020).
[1625] Press Release, The Fed. Rsrv., Federal Reserve Releases a FOMC statement (Mar. 15, 2022).
[1626] *See,* Eric Milstein & David Wessel, *What did the Fed do in response to the COVID-19 crisis?,* THE BOOKINGS INST., Jan. 2, 2024, at Table 1 (listing pandemic-era facilities established by the Fed).
[1627] MARC LABONTE & LIDA R. WEINSTOCK, CONG. RSCH. SERV., R47115, U.S. ECONOMIC RECOVERY IN THE WAKE OF COVID-19: SUCCESSES AND CHALLENGES, AT 2-3 (2022).
[1628] *See,* Eric Milstein & David Wessel, *What did the Fed do in response to the COVID-19 crisis?,* THE BOOKINGS INST. (Jan. 2, 2024) (assessing the Fed's aggressive, unprecedented actions blunted the economic damage of the pandemic); *see also* Celso J. Costa Junior, *et al.*, *Macroeconomic policies and the pandemic-driven recession*, INT'L REV. OF ECON. & FIN. (Mar. 2021) (describing the considerable role QE plays in mitigating a pandemic-driven recession).
[1629] Olivier J. Blanchard & Ben S. Bernanke, *What Cause The U.S. Pandemic-Era Inflation?,* NAT'L BUREAU OF ECON. RSCH. WORKING PAPER SERIES, No. 31417, at 22 (June 2023).
[1630] *Id.*
[1631] *Id.*

By late 2021 and into 2022, inflation had accelerated to levels not seen in decades. The Consumer Price Index and other inflation measures indicated significant price increases across a broad range of goods and services.



The Federal Reserve's early actions, while crucial in preventing economic collapse, also contributed to the inflationary pressures seen later. The prolonged period of low interest rates and large-scale asset purchases, combined with supply chain issues and labor market dynamics, created an environment where inflation could take hold.

The Federal Reserve's aggressive actions during the early stages of the pandemic were vital in blunting the economic damage and facilitating a quicker recovery. However, these same actions, along with other factors like supply chain disruptions and labor shortages, also contributed to the significant inflation observed in late 2021 and 2022. In summary, while the Federal Reserve's use of all available tools helped avert a much longer and more severe economic downturn, it also played a role in the inflationary pressures that emerged later.

FINDING:	After Immediate Actions to Stabilize the Economy and Financial Markets, the Federal Reserve Should Have Placed More Emphasis on Monitoring and Addressing Long-Term Risks Associated with Prolonged Low Interest Rates and

Increased Government Debt and Ensuring that Policies Did Not Lead to Future Financial Instability.

Monitoring and addressing the long-term risks associated with prolonged low interest rates and increased government debt is crucial for maintaining financial stability, especially in the aftermath of a crisis like the COVID-19 pandemic. The Federal Reserve could have better managed these risks and ensured that these policies did not lead to future financial instability.

The Federal Reserve could have produced more detailed and frequent reports on financial stability, focusing on the risks associated with prolonged low interest rates and rising government debt. These reports should have included analyses of asset price bubbles and credit risk within the financial system. Furthermore, implementing robust monitoring systems to track risks across different sectors, including housing, corporate debt, and financial institutions, could have helped identify vulnerabilities early. The Federal Reserve should have conducted regular analyses of government debt sustainability, including assessing the potential impact of rising debt on future interest rates, inflation, and fiscal policy.

The Federal Reserve should have also provided clear forward guidance on how and when it plans to normalize interest rates and unwind unconventional monetary policies. Communicating a well-defined exit strategy would help manage expectations and reduce market uncertainty about future policy changes. Being transparent about the potential risks associated with low interest rates and high government debt would help market participants and policymakers understand the challenges and prepare for potential adjustments. This includes publishing detailed analyses of how current policies could impact future economic conditions.

In summary, the Federal Reserve could have better managed long-term risks associated with prolonged low interest rates and increased government debt by enhancing risk assessment and providing clear communication. These measures would help ensure that policies promote financial stability and avoid creating future vulnerabilities.

FINDING: The Federal Reserve Likely Exceeded Its Role and Responsibilities to Provide Market Liquidity and Acting as a “Lender of Last Resort” by Assuming the Role and Responsibilities of the Department of the Treasury by Acting as a Spender to Prevent Market Insolvency.

The Federal Reserve took unprecedented steps to stabilize the economy, many of which extended beyond its traditional roles and responsibilities. The Federal Reserve's actions to provide market liquidity and act as a "lender of last resort" were crucial in preventing broader economic collapse, but in doing so, it also assumed some roles traditionally associated with the Department of the Treasury.

As explained above, the traditional role of the Federal Reserve is to use monetary policy to influence the economy. The goal is to manage the money supply, control inflation, and stabilize the economy by adjusting interest rates, affecting borrowing and lending, and regulating bank reserves. One the other hand, the Department of the Treasury manages fiscal policy. Fiscal

policy is how the federal government spends money, collects revenue (e.g., taxes), and manages its budget to influence the economy.

The Federal Reserve significantly increased its asset purchases, including Treasury securities and mortgage-backed securities, far beyond the levels seen during previous crises. This expansion was intended to support financial markets and ensure liquidity, but it also led the Federal Reserve to take on a more active role in stabilizing asset prices and market functioning. The Federal Reserve established facilities to purchase corporate bonds, including investment-grade and high-yield bonds, which was a significant departure from its usual practice of focusing primarily on government securities. This move aimed to support *corporate* liquidity and prevent a credit crunch, but it also meant the Federal Reserve was directly involved in private-sector credit markets.

The Federal Reserve's interventions went beyond providing liquidity and began to resemble direct economic support, akin to fiscal spending.[1632] By purchasing corporate bonds and providing loans to businesses and municipalities, the Federal Reserve was effectively injecting capital into the economy, a role traditionally reserved for fiscal authorities.[1633] The Federal Reserve's actions were crucial in preventing a financial crisis, but they also created a situation where market participants came to rely heavily on the Federal Reserve for economic support. This dependence on central bank interventions raised concerns about potential long-term consequences, such as asset price distortions and market inefficiencies.

The Federal Reserve created several novel lending facilities, such as the Main Street Lending Program to provide loans to small and medium-sized businesses, a role typically handled by the Treasury. This program aimed to fill gaps in the financial system by offering loans to businesses that were unable to access traditional credit markets. The Federal Reserve's involvement in this program was more akin to direct fiscal intervention rather than its traditional monetary policy functions.[1634] The Federal Reserve also created the Municipal Liquidity Facility to purchase short-term municipal debt, helping state and local governments manage their liquidity needs. This was a significant expansion of the Federal Reserve's role into state and local government financing, which traditionally falls under the purview of fiscal policy and Treasury activities.

By intervening extensively in markets and assuming roles typically associated with the Treasury, the Federal Reserve risked creating moral hazard—where businesses and investors might come to expect ongoing support from the Federal Reserve, potentially leading to irresponsible risk-taking.[1635] The Federal Reserve's expanded role in economic support and market interventions raised questions about the independence of monetary policy and the potential for political pressures.[1636] The blending of monetary and fiscal policies could affect the

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[1632] Nicolas Cachanosky, *et al*., *The Federal Reserve's response to the COVID-19 contraction: An initial appraisal*, at 1171, SOUTHERN ECONOMIC JOURNAL (Apr. 2021).
[1633] *Id.*
[1634] *Id.*
[1635] Jean-Pierre Zigrand, *et al*., *Moral hazard, the fear of the markets, and how central banks responded to COVID-19,* CTR. FOR ECON. POL'Y RSCH. (Jan. 28, 2021).
[1636] Nicolas Cachanosky, *et al*., *The Federal Reserve's response to the COVID-19 contraction: An initial appraisal*, at 1172-1173, SOUTHERN ECONOMIC JOURNAL (Apr. 2021).

Federal Reserve’s ability to act autonomously in its traditional monetary policy role. The Federal Reserve's actions during the pandemic set new precedents for its role in economic crises. While these actions were maybe necessary to stabilize the economy, they also prompt discussions about the boundaries of central bank interventions and the appropriate roles for monetary and fiscal authorities in future crises.

The Federal Reserve exceeded its traditional role by taking on responsibilities usually associated with fiscal policy, such as direct economic support and market interventions. The Federal Reserve’s expanded actions, including asset purchases and lending programs, were crucial for stabilizing the economy, but they also blurred the lines between monetary and fiscal policy and introduced new risks and challenges and expectations of the Federal Reserve’s role in future crises.

The Societal Impact of Decisions to Close Schools, How the Decisions Were Made and Whether There is Evidence of Widespread Learning Loss or Other Negative Effects as a Result of These Decisions

I. COVID-19 Pandemic-Era School Closures

On March 13, 2020, the CDC released a resource document advising schools on how to implement temporary school closures to contain COVID-19.[1637] Representing AFT, Ms. Weingarten remarked, "[c]losing schools is an agonizing decision, but, with caveats, it's the inevitable and correct one in the midst of this unprecedented national emergency."[1638] Already, schools across the country had begun to transition to remote learning in an effort to stem transmission in the face of enormous pressure from teachers, parents, and teachers unions.[1639]

Accordingly, many public health authorities—including the CDC—supported closing the schools until more could be learned about the novel virus. Still, even the CDC appeared to not be convinced that short- or medium-term school closures would have any substantial impact on transmission, citing data retrieved from Hong Kong and Singapore showing that countries that closed schools did not have more success reducing transmission than places that did not.[1640] Nonetheless, by the end of March 2020, nearly all schools across the country were closed.

On December 8, 2020, in response to then President-Elect Biden's promise to reopen a majority of schools within the first 100 days of his term,[1641] Ms. Weingarten wrote:

> Hallelujah! Unlike Trump, President-elect Biden understands that if we secure the resources and put the public health safeguards in place, we can open schools safely in the second semester—and his first 100 days. This is what visionary, steady and effective leadership during a pandemic looks like. Between this, a vaccine and a Centers for Disease Control and Prevention director who is ready to give national guidance free of political interference, we see a path forward for safe school buildings reopening.[1642]

[1637] Erica Green, *Administration Offers Guidance to Schools as They Shut Down on Their Own*, THE N.Y. TIMES, (Mar. 13, 2020).
[1638] Press Release, Am. Fed'n of Teachers, AFT Says National Schools Shutdown Inevitable Amid Coronavirus Pandemic (Mar. 16, 2020).
[1639] Laura Meckler & Lena Sun, *States are rushing to close schools. But what does the science on closures say?*, THE WASH. POST (Mar. 16, 2020); *See also,* Howard Markel, *Coronavirus School Closings: Don't Wait Until It's Too Late*, THE N.Y. TIMES (Mar. 6, 2020).
[1640] *Considerations for School Closures*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 12, 2020); *See also,* Laura Meckler & Lena Sun, *States are rushing to close schools. But what does the science on closures say?*, THE WASH. POST (Mar. 16, 2020).
[1641] Will Weissert, *Biden vows to reopen most schools after 1st 100 days on job*, ASSO. PRESS (Dec. 8, 2020); *See also,* Erica Green, *Biden Trims Ambitions on School Reopening Pledge*, THE N.Y. TIMES (Feb 11, 2021) (writing that the Biden Administration narrowed President Biden's 100 pledge to apply to K-8 schools and defined reopening to include schools that provided in-person instruction at least one day a week.).
[1642] Press Release, Am. Fed'n of Teachers, AFT's Weingarten on President Biden's Plan to Reopen Schools in First 100 Days (Dec. 8, 2020) (emphasis added).

Unfortunately, many schools across the country were not reopened within 100 days. In fact, only 54 percent of schools K-12 were fully open.[1643] This was despite a desperate attempt by the Biden-Harris Administration to redefine school reopening to include schools that were only open one day per week.[1644]

Instead, many schools remained closed because of AFT and Ms. Weingarten's political interference into the CDC issuance of the Biden Administration's first school reopening guidance entitled "Operational Strategy for K-12 Schools through Phased Prevention" [hereinafter "Operational Strategy"] on February 12, 2021.[1645]

FINDING:	Long Term School Closures Were Not Supported by Available Science and Evidence.

As more data related to COVID-19 became readily available, it was clear that the "science" did not justify school closures. Early data from Wuhan, China—the epicenter of the outbreak—showed that children were unlikely to suffer serious illness or death as a result of COVID-19.[1646] This was later confirmed by CDC data showing that children comprised less than 0.01 percent of hospitalizations and 0.0005 percent of COVID-19 deaths between March 1, 2020 and July 25, 2020.[1647]

Moreover, subsequently acquired data confirmed the CDC's previous suspicion that school closures were unlikely to stem the transmission of COVID-19.[1648] The science indicated that schools were not vectors for viral spread.[1649] Early data from Iceland showed that young children were less likely than adults to transmit COVID-19.[1650] Teachers, individually, were also shown by early data to have no higher risk of infection and of developing serious COVID-19 than other professionals.[1651]

[1643] Press Release, U.S. Dep't. of Education, Statement from U.S. Secretary of Education Miguel Cardona on Results of the March 2021 NAEP Survey on School Reopening (May 6, 2021).
[1644] Morgan Phillips, *Biden's promise to open half the schools in 100 days: Here is how it's going*, FOXNEWS (Feb. 19, 2021); Ebony Bowden, *Biden plan would only reopen half the schools 'one day a week' by end of April*, N.Y. POST (Feb. 9, 2021).
[1645] OPERATIONAL GUIDANCE FOR K-12 SCHOOLS AND EARLY CARE AND EDUCATION PROGRAMS TO SUPPORT SAFE IN-PERSON LEARNING, CTRS. FOR DISEASE CONTROL AND PREVENTION (last updated Oct. 4, 2023).
[1646] The Consequences of School Closures: Intended and Unintended: Hearing Before the H. Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 1 (Mar. 28, 2023) [hereinafter "The Consequences of School Closures: Intended and Unintended"].
[1647] Lindsay Kim, *et al., Hospitalization Rates and Characteristics of Children Aged <18 Years Hospitalized with Laboratory-Confirmed COVID-19 – COVID-New, 14 States, March 1-July 25, 2020*, MMWR (Aug. 7, 2020).
[1648] Scott Atlas, Steve Hanke, Philip Kerpen, & Casey Mulligan, *COVID Lessons Learned: A Retrospective After Four Years,* COMM. TO UNLEASH PROSPERITY (Mar. 2024).
[1649] *See*, Emily Oster, *Schools Aren't Super-Spreaders*, THE ATLANTIC (Oct. 9, 2020).
[1650] Roger Highfield, *Coronavirus: Hunting Down COVID-19*, SCI MUSEUM GROUP (Apr. 27, 2020).
[1651] *Id.*

Comparatively, school closures had an immediate negative impact on students. Many struggled academically[1652] and became especially susceptible to physical[1653] and mental health issues. [1654] These consequences—which only worsened the longer schools remained closed—could hardly have come as a surprise, as previous closures had been understood to result in negative outcomes for students.[1655]

Regrettably, however, these disastrous consequences coupled with evidence that children were unlikely to transmit or suffer serious illness due to COVID-19 were ignored by public health authorities. Instead, many advocates of closures seemingly relied only on favorable data or wrongly attempted to mischaracterize, misrepresent, or exaggerate data.

For example, the CDC published a study from Wood County, Wisconsin to support the proposition that multi-layered mitigation efforts—namely, masking and social distancing—were effective at reducing in-school transmission.[1656] However, these conclusions appear to be a gross exaggeration of the scope of the data, as the study explicitly stated that it did not include a comparative unmasked control group to make such a conclusion.[1657]

Similar studies were not just relied on by public health officials, they were used by teacher unions—specifically AFT—to argue that schools could not be opened safely without multi-layered mitigation efforts, such as masking and social distancing.[1658] In fact, Ms. Weingarten cited the previously noted Wood County, Wisconsin study in her testimony before the Select Subcommittee on April 28, 2023.[1659] This prompted Dr. Tracy Hoeg—one of the senior authors of the study, who testified to the Select Subcommittee on March 28, 2023[1660]—to

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[1652] Rebecca Jack, *et. al.*, *Pandemic Schooling Mode and Student Test Scores: Evidence from U.S. School Districts*, NBER WORKING PAPER SERIES, (Apr. 26, 2022).
[1653] Paulo Puccinelli, *et al.*, *Reduced level of physical activity during COVID-19 pandemic is associated with depression and anxiety levels: an internet-based survey*, BMC PUB. HEALTH, (Mar. 1, 2021); D.S. Burstein, *Cardiopulmonary Exercise Performance in the Pediatric and Young Adult Population Before and During the COVID-19 Pandemic*, PEDIATRIC CARDIOLOGY (May 3, 2022).
[1654] News Release, U.S. Ctrs. for Disease Control & Prevention, New CDC data illuminate youth mental health threats during the COVID-19 pandemic (Mar. 31, 2022).
[1655] Keith Meyers & Melissa Thomasson, *Paralyzed By Panic: Measuring the Effect of School Closures During the 1916 Polio Pandemic on Educational Attainment*, NAT'L BUREAU OF ECON. RES. (Sept. 2017); Chad Aldeman, *Analysis: How Devastating Floods in Thailand in 2011 Harmed Students' Academic Growth, and What Lessons We Can Use in Confronting Learning Loss During the Pandemic*, THE74 (Aug. 18, 2020); Chad Aldeman, *Aldeman: What a Wave of Teacher Strikes in Argentina Can Teach Us About Learning Disruptions, Degree Attainment, Higher Unemployment & Lower Earnings*, THE74 (Aug. 12, 2020); Chad Aldeman, *Aldeman: What a 2005 Earthquake in Pakistan Can Teach American Educators About Learning Loss After a Disaster*, THE74 (July 28, 2020).
[1656] Amy Falk, *et al*., *COVID-19 Cases and Transmission in 17 K-12 Schools—Wood County, Wisconsin, August 31-November 29, 2020, Ctrs. for Disease Control and Prevention,* MMWR (Jan. 29, 2021).
[1657] *Id.; See,* Jay Bhattacharya, *et al.*, *Questions for a COVID-19 Commission*, The Norfolk Grp (Feb. 6, 2023).
[1658] Amy Falk, *et al*., *COVID-19 Cases and Transmission in 17 K-12 Schools—Wood County, Wisconsin, August 31-November 29, 2020, Ctrs. for Disease Control and Prevention,* MMWR (Jan. 29, 2021).
[1659] The Consequences of School Closures, Part 2: The President of the American Federation of Teachers, Ms. Randi Weingarten: Hearing Before the H. Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 1 (Apr. 26, 2023) [hereinafter "The Consequences of School Closures, Part 2"].
[1660] The Consequences of School Closures: Intended and Unintended, *supra* note 1646.

rebuke Ms. Weingarten's conclusion; stating that she ignored the results of the study indicating less than four percent of cases were transmitted at school.[1661]

[1661] Josh Christenson, *Randi Weingarten misrepresented COVID study to Congress, author claims*, N.Y. POST (Apr. 28, 2023).

II. The American Federation of Teachers' Influence

FINDING: The American Federation of Teachers Is Not a Scientific or Medical Organization.

AFT is not a scientific organization—it does not employ epidemiologists or immunologists.[1662] Instead, it is a political union—committed to activism on behalf of its 1.7 million members—that donated $2.4 million dollars to Democrat candidates during the 2020 election cycle. The extent of the AFT's political influence is reflected in the fact that the Biden Administration reached out to AFT for advice on school reopening rather than the AFT reaching out to the Biden Administration:

Ms. Randi Weingarten (April 26, 2023)

Q. …. What did the consultation look like? Did the AFT first engage the CDC or did the CDC reach out to you [the AFT]?

A. So, what essentially happened, sir, was that we were talking to the Biden transition team before he was sworn into office.

*****

Q. Did they reach out to you or…

A. Yes, they reached out. No, the Biden transition team reached out to us and.... [1663]

In a letter to the Select Subcommittee on April 19, 2023, AFT disputed the notion that it had "no scientific expertise."[1664] However, Ms. Weingarten admitted in her testimony before the Select Subcommittee that they did not employ any epidemiologists or immunologists.[1665] The fact that AFT is not a scientific organization is supported by its own employees.

Ms. Kelly Nedrow (Trautner) (June 23, 2023)

Q. You've been at AFT twice and for a number of years. Would you categorize AFT as a scientific or medical organization?

A. AFT is a labor union.[1666]

[1662] *See,* The Consequences of School Closures, Part 2, *supra* note 1659.
[1663] *Id.* at 8-9.
[1664] Letter from Michael Bromwich, Counsel, American Federation of Teachers, to Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic (Apr. 19, 2023).
[1665] The Consequences of School Closures, Part 2, *supra* note 1569.
[1666] Transcribed of Kelly Nedrow, Dir. Health Issues, Am. Fed'n of Teachers, at 19 (June 23, 2023).

Accordingly, "AFT was out of its league" in representing that it had scientific expertise and making policy-based scientific interpretations and recommendations throughout the pandemic.[1667]

FINDING:	The American Federation of Teachers Did Not Support Reopening Schools and Predicated Its Support for Reopening Schools on Non-Scientific Policies.

While AFT and Ms. Weingarten have attempted to rewrite history by arguing that they were always trying to reopen the schools, this simply is not true. AFT continually pushed for school closures throughout the pandemic. Restricting in-person schooling was always the default—not the alternative—mitigation measure underlying AFT's positions.

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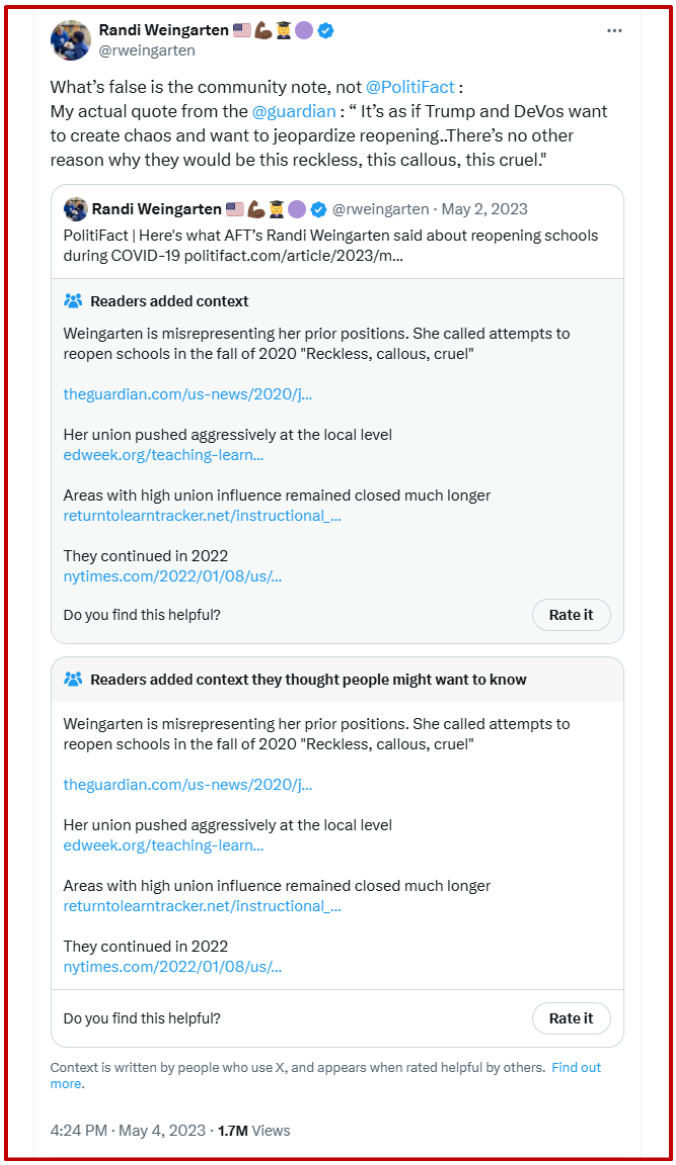
[1667] The Consequences of School Closures, Part 2, *supra* note 1659.


Randi Weingarten
@rweingarten
What's false is the community note, not @PolitiFact :
My actual quote from the @guardian : " It's as if Trump and DeVos want to create chaos and want to jeopardize reopening..There's no other reason why they would be this reckless, this callous, this cruel."
Randi Weingarten @rweingarten · May 2, 2023
PolitiFact | Here's what AFT's Randi Weingarten said about reopening schools during COVID-19 politifact.com/article/2023/m...
Readers added context
Weingarten is misrepresenting her prior positions. She called attempts to reopen schools in the fall of 2020 "Reckless, callous, cruel"
theguardian.com/us-news/2020/j...
Her union pushed aggressively at the local level
edweek.org/teaching-learn...
Areas with high union influence remained closed much longer
returntolearntracker.net/instructional_...
They continued in 2022
nytimes.com/2022/01/08/us/...
Do you find this helpful?
Rate it
Readers added context they thought people might want to know
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nytimes.com/2022/01/08/us/...
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Context is written by people who use X, and appears when rated helpful by others. Find out more.
4:24 PM · May 4, 2023 · 1.7M Views

During the summer of 2020, AFT and Ms. Weingarten attacked the Trump Administration for pushing to return students back to the classrooms for the start of the 2020-2021 school year.[1668] To Ms. Weingarten, incentivizing the reopening of schools was "reckless," "callous," and "cruel."[1669]

AFT released an ad on reopening schools that claimed that students were "being used as guinea pigs."[1670] In an official press release, Ms. Weingarten wrote:

[1668] Press Release, Am. Fed'n of Teachers, AFT's Weingarten Rejects Trump's Schools Reopening Guidelines as Too Little, Too Late (Aug. 12, 2020); Eliza Shapiro, *How Trump's Push to Reopen Schools Backfired*, THE N.Y. TIMES, (Aug. 15, 2020).
[1669] Jessica Glenza, *'Reckless, callous, cruel': teachers' chief denounces Trump plan to reopen schools*, THE GUARDIAN (July 17, 2020).
[1670] Am. Fed'n of Teachers (AFTHQ), *Enough is Enough*, YouTube (Aug. 26, 2020), *available at* https://www.youtube.com/watch?v=svnqsKd8Y4I.

> Schools cannot reopen safely and equitably until we have effectively contained the virus spread and have a robust testing system, a plan for a future surge, and appropriate safety protocols in place, including physical distancing, proper ventilation, deep cleaning procedures and adequate personal protective equipment.[1671]

AFT repeatedly denounced and fought against individual states' plans to reopen schools. AFT even supported efforts by affiliate teacher unions to sue state and local governments attempting to reopen schools for in-person instruction.[1672] In an official press release, Ms. Weingarten wrote:

> The push to reopen schools full time without any precautions or new resources, and, most importantly, amid a skyrocketing COVID-19 surge, ignores science, safety and basic humanity.[1673]

AFT emboldened its affiliates —calling on its members and affiliates to conduct "safety strikes" in some cases.[1674] In a transcribed interview, Ms. Ucelli-Kashyap testified that AFT supported affiliate organizations striking if mitigation measures were not deemed appropriate.[1675]

> **Ms. Marla Ucelli-Kashyap (June 20, 2023)**
>
> Q. Did AFT ever advocate a school district going on strike if a school pushed reopening prior to vaccinations?
>
> A. So, again, you are making me think of resolution language, but we did indicate that when all other possibilities were not being used -- so when appropriate mitigation strategies were not in place,

[1671] Press Release, Am. Fed'n of Teachers, AFT President Randi Weingarten Says Educators Remain Confused over CDC Guidance on School Reopening, Nothing Is Off the Table for Teachers if Schools Aren't Safe (July 24, 2020); *See also, Future of Employability,* AXIOS (Aug. 20, 2020) (Weingarten remarks that "[w]e have an obligation to make remote [learning] better until we can really decrease (coronavirus) community spread throughout the United States, distancing learning and distance working is going to be a fact of life.").

[1672] Press Release, Am. Fed'n of Teachers, Florida educators file lawsuit to stop reckless, unsafe reopening of public school buildings (July 20, 2020); Press Release, Am. Fed'n of Teachers, Educators React to Latest Proceedings in Florida Case on School Reopening (Aug. 13, 2020), Press Release, Am. Fed'n of Teachers, Cypress-Fairbanks AFT Seeks Injunction to Halt Requirement For School Employees to Return to School Buildings (Aug. 14, 2020); Press Release, Am. Fed'n of Teachers, Florida educators win temporary injunction against the executive order (Aug. 24, 2020); Press Release, Am. Fed'n of Teachers, Florida Educators to Appeal Court Ruling, Continue to Fight for Local Control and School Safety (Oct. 9, 2020); Press Release, Am. Fed'n of Teachers, PTU Files Lawsuit Seeking to Close Greene Middle School in Providence (Nov. 2, 2020).

[1673] Press Release, Am. Fed'n of Teachers, Florida puts students, teachers at risk despite union lawsuit (Aug. 17, 2020).

[1674] Resolution, Am. Fed'n of Teachers, Safely Reopening Schools (2020); Speech, Confronting America's Three Crises, AFT President Randi Weingarten (July 28, 2020); Gabrielle Wanneh, *Teachers Union Considers Strikes Over School Reopenings* (July 28, 2020); Valerie Strauss, *New York City Schools closing because of rising coronavirus rates—and so are all schools in Kentucky*, THE WASH. POST (Nov. 18, 2020).

[1675] Ucelli-Kashyap TI, *supra* note 1699, at 66-67.

> when guidance was not being followed when there was reason to suspect harm, that when there was an issue of student and teacher safety, that that might -- there might be situations in which a safety strike would be appropriate. We did not encourage those or call for them, but we indicated that there may be situations in which they would be appropriate.

In response, many of its local affiliates resisted school reopening plans.[1676] For example, the Chicago Teachers Union , tweeted that "the push to reopen schools is rooted in sexism, racism and misogyny" and continued to stage COVID-19 related safety strikes—which necessitated school closures—as late into the pandemic as January 2022.[1677] Another affiliate, the United Teachers of Los Angeles, similarly cited safety concerns throughout the pandemic as to keep schools closed, however, made political demands—not related to COVID-19—including but not limited to enacting a millionaire tax, defunding the police, and providing Medicare for all.[1678]

Finally, in New York City, the New York State United Teachers resisted reopening schools unless Mayor de Blasio agreed to close schools if the COVID-19 positivity rate exceeded three percent—an extremely conservative threshold.[1679] Ms. Weingarten supported the decision to close New York City schools when, predictably, the positivity rate exceeded three percent—seemingly disregarding the advice of the CDC and evidence that transmission was low within schools.[1680] AFT would continue to support efforts within the state to close schools.[1681]

Like their affiliates, AFT relied more on "politics" than "science." In her testimony to the Select Subcommittee, Ms. Weingarten stated that AFT was always working to reopen the school and had released a "commonsense science-based plan to open schools safely."[1682]

The plan Ms. Weingarten was referring to was released April 29, 2020 and entitled "A Plan to Safely Reopen America's Schools and Communities" [hereinafter "AFT Plan"][1683] The AFT Plan could hardly be considered "science based." Among other things, the AFT Plan called on Congress to make significant public investments into areas not related to the pandemic, such as improving broadband infrastructure, increasing Medicaid and SNAP benefits, and cancelling

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[1676] Mike Antonucci, Teacher Union Resistance to Reopening Schools: An Examination of the Largest U.S. School Districts, DEFENSE OF FREEDOM INSTITUTE.
[1677] Mitch Smith & Dana Goldstein, *In a Clash With the Teachers' Union, Chicago Cancels Classes for a Day*, THE N.Y. TIMES (Jan. 4, 2022).
[1678] Mike Antonucci, *supra* note 1676.
[1679] Eliza Shapiro & Dana Rubinstein, *Did It Hit 3%? Why Parents and Teachers Are Fixated on One Number*, THE N.Y. TIMES Nov. 15, 2020; Lauren Camera, *School Reopening Thresholds Vary Widely Across the Country*, U.S. News (Aug. 13, 2020).
[1680] *The Story with Martha MacCallum*, Fox News (Nov. 19, 2020).
[1681] Press Release, Am. Fed'n of Teachers, AFT and NYSUT on Reopening New York State's Schools (Jan. 6, 2021).
[1682] *See,* The Consequences of School Closures, Part 2, *supra* note 1659; *A Plan to Safely Reopen America's Schools and Communities*, American Federation of Teachers (Apr. 29, 2020) [hereinafter "AFT Report"].
[1683] *See,* AFT Report.

student loans.[1684] Specifically, the AFT Plan wrote "COVID-19 has exacerbated the deep inequalities in our society and underscored the need for additional public investments to combat this inequity."[1685] The AFT Plan directed that "[i]t is not the time to be concerned with deficits."[1686]

In addition, the AFT Plan called for limited student testing and a suspension of teacher performance evaluations.[1687] Like those before, these measures—which presumably aimed to combat parental oversight and accountability of America's educators—were not related to science nor combatting the spread of COVID-19 in schools.

FINDING:	The Biden Administration's U.S. Centers for Disease Control and Prevention Broke Precedent and Shared a Draft Guidance with the American Federation of Teachers.

According to testimony, the CDC began drafting the Operational Strategy late December 2020.[1688] In a transcribed interview, Dr. Massetti testified that she was the "lead drafter" of the guidance.[1689] Dr. Massetti testified that the main purpose for drafting the new guidance was to get students back in the classroom.

Dr. Greta Massetti (October 30, 2023)

Q. What was the goal of [the Operational Strategy]?

A. So…we had released several version of school guidance, starting from February 2020. We had done—we had developed resources for schools to provide kind of supportive information about how to provide safe in-person instruction. We'd done a lot of technical assistance, a lot of outreach, webinars, presentations, tools, all through kind of the summer and fall of 2020. And in December, we were very acutely aware that the new school semester was about to start. And we didn't have great data at the time, but to our best estimate, more than half of the school districts in the United States were not providing any in-person instruction at all. We were very concerned about that. We were worried about impact on children. We were worried about a number of concerns. And so we were thinking about what did we need to do to really support schools in reopening for in-person instruction in January, and we were very

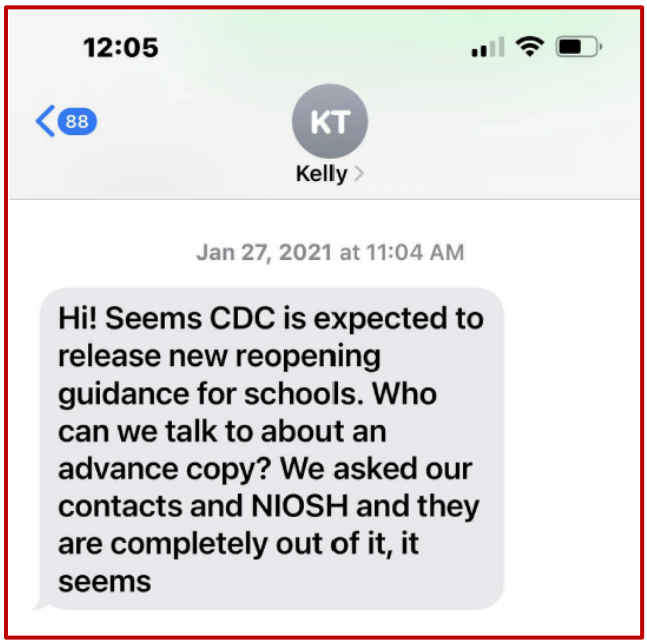
[1684] *A Plan to Safely Reopen America's Schools and Communities*, Am. Fed'n of Teachers (Apr. 29, 2020); *See also,* Letter from Randi Weingarten, President, Am. Fed'n of Teachers, *et. al.*, to U.S. House of Representatives (Apr. 21, 2020).
[1685] *A Plan to Safely Reopen America's Schools and Communities*, *supra* note 1684.
[1686] *Id.*
[1687] *Id.*
[1688] Transcribed Interview of Gretta Massetti, Principal Deputy Dir., Injury Center U.S. Ctrs. for Disease Control and Prevention, at 26 (Oct. 31, 2023) [hereinafter "Massetti TI"].
[1689] *Id.* at 24.

> worried about the possibility that another semester would go by and schools wouldn't be able to take that step…[1690]

By early January 2021, Dr. Massetti testified that she had completed the first draft of the guidance.[1691]

It seems likely that AFT was aware that the CDC—under the newly inaugurated Biden Administration—would be issuing new guidance related to schools. One of President Biden's first acts after being inaugurated was issuing an executive order directing the Department of Education and HHS to develop evidence-based guidance on reopening schools.[1692] Ms. Weingarten commended the act saying that the "order will produce guidance that embeds and disseminates best practices—based on science—for safe and effective in-person, remote and hybrid learning."[1693]

By January 27, 2021, however, AFT was aware that the CDC was preparing new guidance and were anxious to review it. That morning, Ms. Nedrow (Trautner) began inquiring into receiving an "advance copy" of the Operational Strategy.[1694]


12:05
88
KT
Kelly
Jan 27, 2021 at 11:04 AM
Hi! Seems CDC is expected to release new reopening guidance for schools. Who can we talk to about an advance copy? We asked our contacts and NIOSH and they are completely out of it, it seems

[1690] *Id.*
[1691] *Id.* at 26.
[1692] Exec. Order No. 14000, 86 Fed. Reg. 7215 (Jan 26, 2021), *See also, National Strategy for the COVID-19 Response and Pandemic Preparedness*, Pres. Joseph Biden (Jan. 21, 2021).
[1693] Press Release, Am. Fed'n of Teachers, AFT's Weingarten on President Biden's Executive Order on Safely Reopening Schools (Jan. 21, 2021).
[1694] Text from [Redacted], Am. Fed'n of Teachers, to Ms. Kelly Trautner, Am. Fed'n of Teachers (Jan. 27, 2021, 11:04 AM).

Within hours, Ms. Weingarten was connected in an email with members of the Biden-Harris Administration and the White House COVID-19 Response Team to set up a meeting to discuss the guidance in the coming days.[1695]

After coordinating schedules, a call between AFT and the CDC was set up for January 29, 2021.[1696] Dr. Walensky also wanted to participate and was added to the call.[1697] In an email to Ms. Weingarten, Ms. Johnson wrote, "[w]e would really benefit from having the opportunity to hear you and your members perspectives directly."[1698]

In the meantime, AFT staff were scrambling to prepare to review the guidance. On January 28, 2021, Ms. Ucelli-Kashyap—who was also a member of the Biden Transition team[1699]—emailed other AFT staff to be ready to serve as "rapid reviewers" of the new guidance.[1700] Specifically, providing a "quick summary of what it does and doesn't say, and how that purports with our must haves, et cetera."[1701]

The next day, January 29, 2021, Ms. Ucelli-Kashyap followed up with her team regarding her instructions, which she wrote was likely going to be released the following Monday, February 1, 2021, informing the team that hopefully she would have more information following the call between AFT and Ms. Weingarten later that afternoon:[1702]

Message

From: Marla Ucelli-Kashyap, Educational Issues [redacted]
Sent: 1/29/2021 4:54:13 PM
To: Robin Vitucci, Educational Issues [redacted] Chelsea Prax, Educational Issues [redacted] Justin Stone, Educational Issues [redacted]
CC: Giselle Lundy-Ponce, Educational Issues [redacted] Shital Shah, Educational Issues [redacted]
Subject: UPDATE RE upcoming CDC guidancd

Hi All,
It new seems likely that the guidance will be out Monday, definitely sometime next week. Kelly and I are joining Randi in a call with a Biden staff and the head of the CDC this afternoon. Hopefully I will have something to report after that.
marla

FINDING: The American Federation of Teachers Advocated for Mitigation Measures that Were Overly Broad and Not Scientific, including Closure Triggers, Delaying the

[1695] E-Mail from Carmel Martin, Policy Advisor, The White House, to Randi Weingarten, President, Am. Fed'n of Teachers, *et. al*. (Jan. 29, 2021).
[1696] E-Mail from Carole Johnson, Testing Coordinator, COVID-19 Response Team, The White House, to Randi Weingarten, President, Am. Fed'n of Teachers (Jan. 29, 2021).
[1697] *Id*.
[1698] *Id*.
[1699] Transcribed Interview of Marla Ucelli- Kashyap, Dir., Am. Fed'n of Teachers, at 9, 46 (June 20, 2023) [hereinafter "Ucelli-Kashyap TI"].
[1700] E-Mail from Marla Ucelli-Kashyap, Senior Dir., Am. Fed'n of Teachers, to Robin Vitucci, Am. Fed'n of Teachers, *et al*. (Jan. 28, 2021).
[1701] *Id*.
[1702] E-Mail from Marla Ucelli-Kashyap, Senior Dir., Am. Fed'n of Teachers, to Robin Vitucci, Am. Fed'n of Teachers, *et al.* (Jan. 29, 2021).

U.S. Centers for Disease Control and Prevention's Issuance of the Operational Strategy.

While AFT was uncertain of the specifics of the guidance, they knew what they wanted to see included in it. Among other things, AFT wanted the CDC to implement a "trigger" that would automatically cause schools to close if COVID-19 positivity rate exceeded a certain threshold.[1703] These priorities were included in meeting notes prepared for Ms. Weingarten for her phone call with Dr. Walensky on January 29, 2021.[1704]

NOTES: Dr. Walensky and COVID call – 01/29/2021

Note that the guidance needs to be clear and easy to understand. Imagine it being read by a social studies teacher or a parent.This is a real opportunity for a powerful reset and return to the credibility the CDC has traditionally held.

1. **Need robust testing included; it's a real stumbling block in most places.** Robust surveillance testing programs that will conduct random samples of students and staff and contact tracing. This is about resources but also about the "how" for districts to stand up a program and staff and carry it out.
2. **Emphasize 6' as measure for physical distancing.** Another contentious issue in the field, and another where we need CDC to weigh in.
3. **Enhance masking recommendations.** N-95's or comparable masks/respirators for school staff for better protection from the new variants, even though they haven't modified their guidance on masks yet.
4. **Accommodations for educators and school staff who are high-risk, or who have a high-risk household member, are a must.** Guidance should address the unique occupational concerns of adults in a school setting - their increased risks of serious illness if infected compared to students. While there is overlap in the safety concerns for both students and staff; adults have unique concerns - they need accommodations for their personal underlying conditions and for those of family members with whom they reside or for whom they have a significant care-giving role.
5. **Provide a recommended positivity rate threshold.** This is a contentious issue in the field, and one where we need CDC to weigh in. We need an objective metric for closure/reopen triggers.[I liked Kelly's addition of a bright-line metric.]
6. **CDC should recommend stakeholder involvement/committees to oversee reopening and monitor throughout pandemic to counter mistrust and fear.** Addition of a process recommendation that key stakeholders - educators, unions, parents and public health departments etc - form district-wide committees to plan/implement school reopening and monitor the schools on a routine basis and help determine when schools should reopen and close and reopen again. School districts must counter mistrust and fear with involvement and transparency. It's not only educators and school staff that are reluctant to return but also a large percentage of students of color (they have not returned to NYC schools at a high rate compared to white students) - their parents are fearful of their exposure. Only genuine, active involvement of these key stakeholders to actively monitor the situation and assist in assuring mitigation strategies are in place and making decisions to close schools and reopen will be an antidote to that push-back.

According to Dr. Massetti, AFT made additional requests during the January 29 phone call, including a recommendation that schools should not be reopened unless teachers were fully vaccinated.

[1703] Notes prepared by staff, for Ms. Weingarten, for call with Dr. Walensky (week of Jan. 1, 29, 2021) (on file with Subcomm).
[1704] *Id.*

Dr. Greta Massetti (October 31, 2023)

Q. What were the additional requests [AFT made], if you can remember?

A. So they very strongly advocated for strengthening our recommendations around vaccination and in particular were encouraging CDC to recommend that schools should not be reopened for in-person instruction unless teachers were all fully vaccinated. We did not accept that guidance.

They also were strongly recommending that schools should not reopen or that CDC should say schools should not reopen unless they upgraded their ventilation, HVAC.

And for both of those recommendations we actually made it clear that schools did not to have all teachers vaccinated or have upgrade ventilation to provide in-person instruction.

They also wanted us to specify the types of masks that should be required, in particular respirators or more protective masks. We did not accept that recommendation.

And they had also recommended that we should specify that 6 feet of physical distance should be a minimum requirement but it really should be higher than that when possible. [1705]

Dr. Massetti understood that certain things AFT advocated for would have made openings more difficult.

Dr. Gretta Massetti (October 31, 2023)

Q. The four kind of larger recommendations that they made previously—vaccinations, ventilation, masks, and the 6-foot minimum—if those were implemented, would fewer schools have opened?

A. It's hard to kind of entertain a hypothetical. It would have made reopening more challenging for schools certainly, yes.[1706]

[1705] Massetti TI, *supra* note 1688, at 43.
[1706] Massetti TI, *supra* note 1688, at 57.

Among its other priorities, AFT advocated that the guidance included a closure "trigger" that would automatically close schools if the positivity rate of COVID-19 exceeded a certain threshold. Ms. Ucelli-Kashyap testified regarding how AFT interpreted closure triggers to work.

Ms. Ucelli-Kashyap (June 20, 2023)

Q. If you recall or are able to describe just generally, what is a closure trigger?

A. That would be a measure of viral prevalence or spread that would cause or trigger a decision to not operate fully in person.[1707]

These "triggers" were not only desired by AFT, but other teachers unions across the country. As previously noted, New York City teachers were able to negotiate with Mayor de Blasio to implement a closure "trigger" threshold of a three percent positivity rate.[1708]

Dr. Massetti testified that the CDC never recommended a closure trigger and that there was no "scientific evidence" supporting such a mitigation measure.[1709]

Dr. Greta Massetti (Oct. 31, 2023)

Q. Did the CDC ever evaluate a closure trigger or a closure threshold?

A. We never recommended a closure trigger or closure threshold. When it was recommended. We assessed the evidence and did not feel that there was any scientific evidence to suggest that one was necessary.[1710]

Dr. Walensky testified that AFT had requested that closure "triggers" be included in the Operational Strategy, but that it was not accepted because the goal of the guidance was to open schools—not close them.

Director Rochelle Walensky (June 13, 2023)

Q. [D]id the American Federation of Teachers provide suggested edits to the [Operational Strategy], including a trigger to automatically close schools, that if implemented, would have kept more schools closed and kids out of the classroom?

A. The AFT was interested in having closure triggers. That is my understanding, yes.

[1707] *See*, Ucelli-Kashyap TI, *supra* note 1699, at 26.
[1708] *Id.*
[1709] *See*, Massetti TI, *supra* note 1688, at 63.
[1710] *Id.*

…

Q. Did the AFT's suggested closure trigger run contrary to the prevailing science and data at that time?

A. Again, this was something where we had layered mitigation strategies in the operational guidance to keep our schools open…our goal was not to talk about school closure triggers. Our goal in this guidance was to keep them open.[1711]

According to documents reviewed by the Select Subcommittee, the initial feedback from AFT and other teacher unions made it unlikely that the CDC would be able to release the Operational Strategy according to the previously planned release date of February 3, 2021.[1712]

From: Berger, Sherri (CDC/OCOO/OD)
Sent: Sat, 30 Jan 2021 00:39:14 +0000
To: O'Connell, Dawn (HHS/IOS); Pearlman, Aj (HHS/IOS); Despres, Sarah (HHS/IOS); Johnson, Carole A. EOP/WHO
Cc: Jones, Christopher M. (CDC/DDNID/NCIPC/OD); Schuchat, Anne MD (CDC/OD); Walensky, Rochelle (CDC/OD); Walke, Henry (CDC/DDID/NCEZID/DPEI)
Subject: RE: Revised: Draft School Guidance

Quick update: Rochelle and Carole started teacher union calls today. I think there may be one more to schedule on Monday. Based on the feedback, at this time, its not looking like Wednesday will work to roll out the new guidance. Thank you
(And, a HUGE thank you [redacted]

AFT's feedback was also apparently serious enough to necessitate the CDC scheduling another meeting with AFT staff to discuss the Operational Strategy the following Monday, February 1, 2021.[1713]

It is unclear when the CDC initially decided that they would be open to accepting suggestions and edits in the guidance from AFT. According to emails reviewed by the Select Subcommittee, Ms. Nedrow (Trautner) wrote to Ms. Weingarten that the CDC "did not seem to be super open to suggested edits" on January 31, 2021.[1714] On February 1, 2021, Ms. Nedrow (Trautner) again emailed Ms. Weingarten writing that "it seems very unlikely any of our changes will be incorporated because the document is mostly through their internal review process."[1715]

[1711] *See,* The Consequences of School Closures, Part 2, *supra* note 1659.
[1712] E-Mail from Sherri Berger, Ctr. for Disease Control and Prevention, to Dawn O'Connell, Dep't. of Health and Human Serv., *et. al.* (Jan. 30, 2021).
[1713] *Id.*
[1714] E-Mail from Kelly Trautner, Am. Fed'n of Teachers, to Randi Weingarten, President, Am. Fed'n of Teachers, *et. al.* (Feb. 1, 2021, 6:27 PM).
[1715] *Id.*

Another AFT employee, Ms. Chelsea Prax, seemed less enthusiastic after the follow-up meeting with the CDC on February 1, 2021, writing in an email to colleagues that "it's not clear that CDC wanted feedback, despite their "we're listening" opening comments."[1716] However, Ms. Prax openly wondered if AFT was pursing "other dialogues" with the Biden-Harris Administration related to the guidance.[1717]

From: Chelsea Prax, Educational Issues
Sent: Monday, February 1, 2021 2:38 PM
To: Marla Ucelli-Kashyap, Educational Issues
Subject: RE: Key takeaways: CDC document

Hmm … it's not clear that CDC *wanted* feedback, despite their "we're listening" opening comments.

I would appreciate any insights on how – or whether – that 30min is related to other dialogues with federal agencies/Biden administration. I get the impression that it was far afield from how Jane/Beth are (would like to be) engaging ED.

Thanks, C

Regardless, it is hardly surprising that AFT staff may have felt that the CDC was not open to their feedback. AFT staff clearly were not satisfied with the guidance and believed that its mitigation measures did not go far enough.

According to emails reviewed by the Select Subcommittee, Dr. Walke described the follow-up meeting with AFT staff on February 1, 2021 as "difficult."[1718] Specifically, Dr. Walke wrote that "it seemed as though the staff had not read it, confused it with another document, or perhaps, did not understand the intent."[1719] Among other things, AFT wanted the guidance to support more testing, ventilation standards, and enforcement mechanisms for mitigation efforts.[1720]

Dr. Massetti testified that the type of feedback received from AFT made the call difficult.

Dr. Greta Massetti (Oct. 31, 2023)

Q. Can you explain what made the call difficult?

A. …[T]he type of feedback they gave was inconsistent with what we had heard from other partners. And in particular they were encouraging us to incorporate a lot of language in the guidance that really is not CDC's kind of scope.

[1716] E-Mail from Chelsea Prax, Am. Fed'n of Teachers, to Marla Ucelli-Kashyap, Am. Fed'n of Teachers (Feb. 1, 2021, 2:38 PM).
[1717] *Id.*
[1718] E-Mail from Henry Walke, Ctr. for Disease Control and Prevention, to Sherri Berger, Ctrs. for Disease Control and Prevention, Carole Johnson, Testing Coordinator, COVID-19 Response Team, The White House (Feb. 1, 2021, 8:03 PM).
[1719] *Id.*
[1720] *Id.*

***

Q. On the call, if you remember, what did they mean by, "Wanted enforcement mechanisms for mitigation efforts in schools"?

A. I think they wanted for us to be able to—or for CDC to mandate—or had made suggestions that CDC could require wearing masks, things like that. But we really don't have any authority and would not be able to make those kinds of recommendations.[1721]

FINDING: The U.S. Centers for Disease Control and Prevention Accepted American Federation of Teachers Edits to the Operational Strategy.

According to documents and communications reviewed by the Select Subcommittee, Dr. Walensky asked Ms. Weingarten and AFT to provide explicit language during the January 29, 2021 meeting.[1722]

From: Kelly Trautner, Health Issues
Sent: Friday, January 29, 2021 6:43 PM
To: Marla Ucelli-Kashyap, Educational Issues; Jane Meroney, Legislation; Beth Antunez, Legislation; Sarah Tammelleo, Research & Strategic Initiatives; Kyle Arnone, Research & Strategic Initiatives; amy bahruth; Darryl Alexander, [redacted] Consultant, Office of the Secretary-Treasurer
Subject: CONFIDENTIAL: CDC K-12 Operational Strategy

PLEASE DO NOT SHARE THIS BEYOND ESSENTIAL AFT STAFF. We were given an advance draft of the CDC's guidance, set to be released next Wednesday. Amy and Darryl are reviewing now, we will share impressions.
In the meantime, we also have another (somewhat overlapping) group working on the accommodation language Dr. Walensky asked Randi for today.
<DRAFT K-12 Schools Operational Strategy 2021.pdf>
<2021.01.29 walensky call notesREV.docx>

Dr. Massetti testified that, while the CDC invites input from stakeholders, it is not obliged to accept edits.

Dr. Greta Massetti (October 31, 2023)

Q. Would those outside groups be given the opportunity to edit or provide comment [on draft guidance]?

A. Yes. And generally we invited comments or requests for clarification, but we—our standard practice was to make it clear that we would consider any inputs, but we were not obligated to make changes based on those inputs.

Q. Did you ever receive line-by-line edits from any of the outside groups on the school reopening guidance?

[1721] Massetti TI, *supra* note 1688, at 51-51.
[1722] E-Mail from Kelly Trautner, Am. Fed'n of Teachers, to Marla Ucelli-Kashyap, Am. Fed'n of Teachers, *et. al.* (Jan. 29, 2021, 6:43 PM).

A. Could I get some clarification on what you mean—how you would define a line-by-line edit?

Q. Like a traditional, like, strike and replace or a traditional we need this specific line added. Not like general ideas or thoughts, but actual—the outside group providing language.

A. Yes, sometimes we had outside groups providing language, yes.[1723]

Dr. Massetti's testimony is seemingly contradicted by Dr. Walke who testified that, while the CDC often receives comments and suggestions from outside partners, it is "uncommon" for outside partners to send line-by-line edits. Dr. Walke also testified that it was "uncommon" for the CDC to "incorporate" such edits.

Dr. Henry Walke (February 18, 2022)

Q. So, knowing that it's uncommon to send draft guidances outside the government, is it uncommon for outside groups to send draft language to…the CDC?

A. It's uncommon.

…

Q. Uncommon for, like, line-by-line edits or additions?

A. That's correct.

…

Q. In general, if an outside group send [the CDC] a line-by-line edit, do you think it is appropriate to accept it?

A. As I have said before, it would be uncommon for us to incorporate line-by-line edits into our guidance.[1724]

On February 1, 2021, Ms. Nedrow (Trautner) sent a follow-up email to staff at the White House and the CDC.[1725] Ms. Nedrow (Trautner) then provided proposed language on behalf of

[1723] *See*, Massetti TI, supra note 1688.
[1724] Transcribed Interview of Henry Walke, M.D., U.S. Ctrs. Disease Control and Prevention, at 60-61 (Feb. 18, 2022).
[1725] E-Mail from Kelly Trautner, Am. Fed'n of Teachers, to Ms. Carole Johnson, Testing Coordinator, COVID-19 Response Team, The White House, *et. al.* (Feb. 1, 2021, 7:27 PM) (hereinafter AFT Edit 1).

Ms. Weingarten that included several accommodations "to limit the risk of workplace exposure."[1726] [hereinafter "AFT Edit 1"].[1727]

From: Kelly Trautner, Health Issues [redacted]
Sent: Monday, February 1, 2021 7:27 PM
To: Johnson, Carole A. EOP/WHO [redacted] Martin, Carmel EOP/WHO [redacted] Gershman, Lynn E. (CDC/OD/OCS) [redacted] Tracey-Mooney, Maureen EOP/WHO [redacted] McIntee, William T. EOP/WHO [redacted] Okolo, Osaremen F. EOP/WHO [redacted] Gonzalez, Noe EOP/WHO [redacted]
Cc: Michelle Ringuette, Office of the President [redacted] Jane Meroney, Legislation [redacted] Beth Antunez, Legislation [redacted] Marla Ucelli-Kashyap, Educational Issues [redacted]
Subject: [EXTERNAL] AFT Follow-up

Good evening, Colleagues:

Thank you again for Friday's rich discussion about forthcoming CDC guidance and for your openness to the suggestions made by our president, Randi Weingarten, and the AFT. We are hopeful that lines of communications will remain open, and that we can serve as a true thought partner as you continue the important work toward safe reopening of schools.

You will recall that Randi committed to provide Dr. Walensky and the group with suggested language on the issue of accommodations for staff who are either themselves in the high-risk category, or for those who reside with a high-risk individual. We crafted the language below using a NIOSH document, as well as language in some of our agreements with school employers. Thank you for considering it.

- Employers should provide reassignment, remote work, or other options for staff who have documented high-risk conditions or who are at increased risk for severe illness from COVID-19 to limit the risk of workplace exposure. Options for reassignment include telework, virtual teaching opportunities, modified job responsibilities, environmental modifications, scheduling flexibility, or temporary reassignment to different job responsibilities. These options should likewise be extended to staff who have a household member with documentation of a high-risk condition or who are at increased risk for severe illness from COVID-19. Policies and procedures addressing issues related to teachers and other staff at higher risk of serious illness should be made in consultation with occupational medicine and human resource professionals, keeping in mind Equal Employment Opportunity (EEO) concerns.

Finally, we were able to review a copy of the draft guidance document over the weekend and were able to provide some initial feedback to several staff this morning about possible ways to strengthen the document. We are grateful for the agency's effort to bring some measure of organization and framework to guidance. We are likewise grateful for the inclusion of some of the mitigation efforts we have been calling for since last year. It is our hope that we can be engaged early in the process moving forward, as we believe our experiences on the ground can inform and enrich thinking around what is practicable and prudent in future guidance documents.

Please do not hesitate to reach out should you have questions or desire additional dialogue.

Warm regards,

Kelly

Kelly D. Trautner
Director | Health Issues
(she/her/hers)
T: [redacted] | F: [redacted] | E: [redacted]

American Federation of Teachers, AFL-CIO
555 New Jersey Ave. N.W. | Washington, DC 20001 | [redacted]

On February 3, 2021, Dr. Walensky replied to Ms. Nedrow (Trautner) to inform her that the accommodation language was being "worked" into the guidance.[1728]

[1726] *Id.*
[1727] *Id.*
[1728] E-Mail from Dr. Rochelle Walensky, Dir., U.S. Ctrs. For Disease Control & Prevention, to Carole Johnson, Testing Coordinator, COVID-19 Response Team, The White House, *et. al.* (Feb. 3, 2021, 5:04 PM).

Message

From: Walensky, Rochelle (CDC/OD) [redacted]
Sent: 2/3/2021 5:04:41 PM
To: Johnson, Carole A. EOP/WHO [redacted] Berger,Sherri (CDC/OCOO/OD) [redacted] O'Connell, Dawn (HHS/IOS) [redacted]
CC: Martin, Carmel EOP/WHO [redacted] Tracey-Mooney,Maureen EOP/WHO [redacted] McIntee, William T.EOP/WHO [redacted] Okolo, Osaremen F. EOP/WHO [redacted] Gonzalez, Noe EOP/WHO [redacted] Cc: Michelle Ringuette, Office of the President [redacted] Jane Meroney, Legislation [redacted] BethAntunez, Legislation [redacted] Marla Ucelli-Kashyap, Educational Issues [redacted]
Subject: RE: AFT Follow-up

Dear All,
I just wanted to circle back and extend my gratitude for the language you have provided us below. Regrets for my delay in reply but I wanted to be certain you knew it is being worked into (with just a few small tweaks) the school opening guidance. We have also included the executive summary you suggested.
Please know we are listening and working hard to ensure your confidence and partnership in this endeavor.
My very best,
Rochelle

Thereafter, AFT Edit 1 made it into the final Operational Strategy largely unchanged:

AFT PROPOSED LANGUAGE "AFT EDIT 1"	**OPERATIONAL STRATEGY FINAL VERSION**
Employers should provide reassignment, remote work, or other options for staff who have documented high-risk conditions or who are at increased risk for severe illness from COVID-19 to limit the risk of workplace exposure. Options for reassignment include telework, virtual teaching opportunities, modified job responsibilities, environmental modifications, scheduling flexibility, or temporary reassignment to different job responsibilities. These options should likewise be extended to staff who have a household member with documentation of a high-risk condition or who are at increased risk for severe illness from COVID-19. Policies and procedures addressing issues related to teachers and other staff at higher risk of serious illness should be made in consultation with occupational medicine and human resource professionals, keeping in mind Equal Employment Opportunity (EEO) concerns.	At all levels of community transmission, **employers should provide reassignment, remote work, or other options for staff who have documented high-risk conditions or who are at increased risk for severe illness from COVID-19 to limit the risk of workplace exposure**. When these conditions are disabilities under the Americans with Disabilities Act, employers must provide reasonable accommodations subject to undue hardship. **Options for reassignment** may include by are not limited to **telework, virtual teaching opportunities, modified job responsibilities, environmental modifications, scheduling flexibility, or temporary reassignment to different job responsibilities. These options should likewise be extended to staff who have a household member with a high-risk condition or who are at increased risk for severe illness from COVID-19. Policies and procedures addressing issues related to teachers and other staff at higher risk of serious illness** and the application of reassignment, remote work or other options for mitigation **should be made in consultation with occupational medicine and human resource professionals** with knowledge of the specific situation, **keeping in mind Equal Employment Opportunity (EEO)** and other potential legal **concerns**.

The inclusion of the accommodation language was not enough for AFT. According to emails reviewed by the Select Subcommittee, Dr. Walensky had a call with Ms. Weingarten on February 7, 2021.

On the morning of February 10, 2021, AFT was able to review a copy of the Operational Strategy that was leaked to *The New York Times*.[1729] AFT staff quickly expressed concern that the Operational Strategy draft allowed for schools to be open at any level of community transmission.[1730] In relevant part, the draft language directed:[1731]

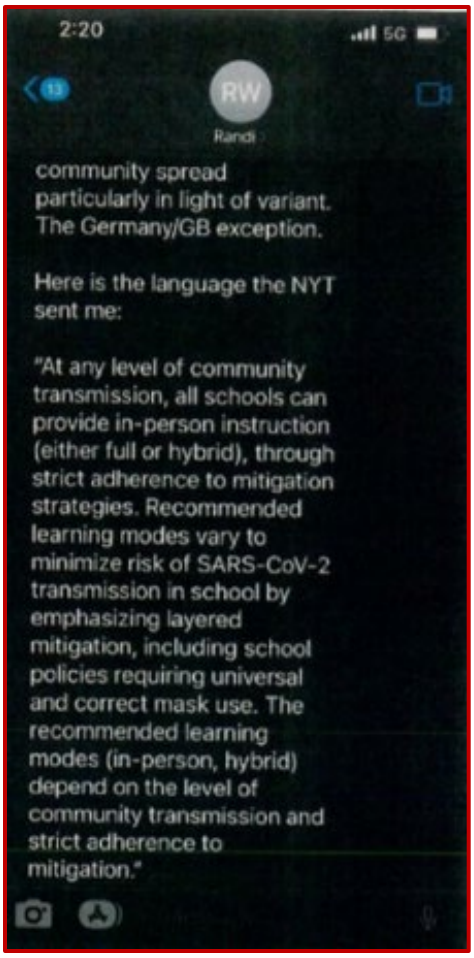
> At any level of community transmission, all schools can provide in-person instruction (either full or hybrid), through strict adherence to mitigation strategies. Recommended learning modes vary to minimize risk of SARS-CoV-2 transmission in school by emphasizing layered mitigation, including school policies requiring universal and correct mask use. The recommended learning modes (in-person, hybrid) depend on the level of community transmission and strict adherence to mitigation.[1732]

AFT—specifically, Ms. Weingarten—was not pleased that Operational Strategy would allow schools to open at any level of community transmission. On the morning of February 11, 2021, Ms. Weingarten texted her concerns to Dr. Walensky, asking for a meeting after the Operational Guidance was leaked.[1733] Dr. Walensky responded that she could meet that afternoon.[1734]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1729] E-Mail from Marla Ucelli-Kashyap, Am. Fed. of Teachers, to Justin Stone, Am. Fed. of Teachers, *et. al.* (Feb. 10, 2021, 1:52 PM).
[1730] *Id.*
[1731] *Id*. (emphasis added).
[1732] *Id.*
[1733] *Newly Revealed Texts Show Relationship Between Teachers Unions, Biden's CDC,* FAIRFAX REPUBLICANS (June 5, 2023).
[1734] *Id.*

2:19
5G
RW
Randi
iMessage
Hi . it's Randi.We heard something from a NYT leak that seemed at odds with discussion. Do you have time for a call
Hmmm. Argh. In a wall of meetings. Can touch base this afternoon. Are you able to ping what you learned?
Yes.. let me get
This was leaked by someone in agency to NYT: they are running with a full speed ahead angle.
I told NYT we were looking for a metric like WHO has 4 school closure if high community spread particularly in light of variant.


2:20
5G
RW
Randi
community spread particularly in light of variant. The Germany/GB exception.
Here is the language the NYT sent me:
"At any level of community transmission, all schools can provide in-person instruction (either full or hybrid), through strict adherence to mitigation strategies. Recommended learning modes vary to minimize risk of SARS-CoV-2 transmission in school by emphasizing layered mitigation, including school policies requiring universal and correct mask use. The recommended learning modes (in-person, hybrid) depend on the level of community transmission and strict adherence to mitigation."

Shortly after the text exchange between Ms. Weingarten and Dr. Walensky, Ms. Nedrow (Trautner) emailed Dr. Walensky expressing AFT's concerns with the guidance and provided another edit.[1735] Ms. Nedrow (Trautner) stated that AFT was "deeply concerned" about the language and stated that AFT did not "believe that any current research ha[d] demonstrated that all schools…can safely reopen."[1736]

From: Kelly Trautner, Health Issues [redacted]
Sent: 2/11/2021 4:25:06 PM
To: Rochelle Walensky; Johnson, Carole A. EOP/WHO [redacted]; Sherri Berger; Dawn O'Connell; Martin, Carmel EOP/WHO [redacted]; Tracey-Mooney, Maureen EOP/WHO [redacted]; McIntee, William T. EOP/WHO [redacted]; 'Okolo, Osaremen F. EOP/WHO' [redacted]; Gonzalez, Noe EOP/WHO [redacted]
CC: Randi Weingarten, Office of the President [redacted] Jane Meroney, Legislation [redacted]; Marla Ucelli-Kashyap [redacted]; Beth Antunez, Legislation [redacted]
Subject: RE: AFT Follow-up

Dr. Walensky:
Thank you for your continued openness to our suggestions and input. We would like to share some thoughts regarding the paragraph below which was apparently leaked from the imminent guidance on reopening schools:

"At any level of community transmission, all schools can provide in-person instruction (either full or hybrid), through strict adherence to mitigation strategies. Recommended learning modes vary to minimize risk of SARS-CoV-2 transmission in school by emphasizing layered mitigation, including school policies requiring universal and correct mask use. The recommended learning modes (in-person, hybrid) depend on the level of community transmission and strict adherence to mitigation."

It would be great to see the insertion some variation of the following: "In the event high-community transmission results from a new variant of SARS-CoV-2, a new update of these guidelines may be necessary."

We are deeply concerned about likely implications this language will have in schools where strict adherence to mitigation strategies is lacking or is impossible to implement, particularly those schools in high-density, crumbling infrastructure areas, and particularly when community transmission is high. We don't believe that any current research has demonstrated that all schools in those areas can safely reopen.

In light of the new variants of the virus, we are concerned the absence of a closure threshold might put safety of adults and kids in school settings. There is not yet conclusive research to support that keeping schools open in those countries would have been a safe decision, though the Imperial London model seems to show infections among secondary school students in the UK spiked when the new variant began to spread. And we also know that, while infection rates are beginning to drop, the BII7 variant is expected to cause a sharp uptick in infections- even becoming the predominant variant by March. The UK was forced to close schools in the wake of the variant spread; Germany had to make a similar decision to close schools. When teachers and school staff see that travel restrictions are being considered in the U.S., we expect even more hesitation about in-person learning. Even a "variant closing metric" would go a long way in allaying hesitation and fears related to reopening.

We really want to lend our efforts to helping restore faith in the CDC, and we believe you are off to a great start. We must, however, urge the inclusion of clear closure triggers in the imminent guidance. Provisions providing for when schools should close, like what is in place in New York City, instill some degree of confidence for those who are hesitant about returning to school. Embedding such a threshold bolsters transparency and is a must for ensuring parents and administrators can plan for a surge like we have seen in Great Britain and in Germany.

We look forward to continued collaboration with you and your team.

Kelly

Kelly D. Trautner
Senior Director | Health Issues

[1735] E-Mail from Ms. Kelly Trautner, American Fed. Of Teachers, to Dr. Rochelle Walensky, Dir., U.S. Ctrs. For Disease Control & Prevention, *et. al.* (Feb. 11, 2021, 4:25 PM).
[1736] *Id.*

Ms. Nedrow (Trautner) then provided language that would permit the CDC to update the Operational Strategy in the event of a new SARS-CoV-2 variant [hereinafter "AFT Edit 2"].[1737]

> In the event high-community transmission results from a new variant of SARS-CoV-2, a new update of these guidelines may be necessary.

These edits were intended to make it more likely that schools would close to in-person learning. According to Ms. Nedrow's (Trautner) email to Ms. Weingarten, the draft language was meant to address AFT's concerns about the absence of "triggers" that would automatically cause schools to close.[1738] Specifically, the AFT advised Dr. Walensky that its draft language should be incorporated to remediate "the absence of a closure threshold" and AFT's continued efforts to "urge the inclusion of clear closure triggers in the imminent guidance."[1739]

On February 11, 2021, Ms. Ucelli-Kashyap told her colleagues that the guidance would not include "a closing metric, but there may be some useful nuanced language there."[1740] Ms. Nedrow (Trautner) testified that the edit was not "necessarily rooted in science."

> **Ms. Kelly Nedrow (Trautner) (June 23, 2023)**
>
> Q. I'm just wondering why [the suggested change] is necessary…considering the CDC was already qualifying that schools could go hybrid learning if they needed to and had to follow all the mitigation strategies that CDC was advocating for, which at that time and throughout the pandemic has been masking and social distancing and the other things that you've talked about. So I just don't understand why adding the qualifier was scientifically necessary.
>
> A. So…we had two top priorities. One was making sure that the environment was safe. The other was making sure that our members felt safe, which isn't necessarily rooted in science, but, practically speaking, was necessary to get people to be willing to go back into buildings, and that was the thrust of this sentence that we recommended.
>
> Q. So there was no science supporting that sentence; it was strictly to persuade your members to go back to school?

[1737] *Id*.
[1738] E-Mail from Kelly Trautner, American Fed. Of Teachers, to Rochelle Walensky, M.D., Dir., U.S. Ctrs. For Disease Control & Prevention, *et. al.* (Feb. 11, 2021, 4:25 PM).
[1739] *Id*.
[1740] E-Mail from Ucelli-Kashyap, Am. Fed. of Teachers, to Rob Well, Am. Fed. of Teachers, *et. al.* (Feb. 11, 2021, 5:46 PM).

A. We knew that the CDC—we were pretty certain the CDC would update guidance if it needed to update guidance.[1741]

Additionally, Ms. Nedrow (Trautner) testified that "everything" that was proposed for the guidance was cleared by Ms. Weingarten.

Ms. Kelly Nedrow (Trautner) (June 23, 2023)

Q. Did you ever have a conversation with Ms. Weingarten about a closure threshold or a closure trigger?

A. About—with respect to the CDC guidance?

Q. Um-hum.

A. I mean, we discussed it. Everything that was in the emails in the record was discussed with our President. There was no position that we took that was not okayed by our President.[1742]

According to documents reviewed by the Select Subcommittee, Ms. Weingarten had a call with Dr. Walensky regarding the guidance shortly after the guidance was leaked.[1743] Later that night, Ms. Weingarten and AFT staff also had a "Confidential Briefing" with members of the Department of Education as well as the CDC.[1744]

While the specific content of those calls is unknown, Dr. Walensky directed her staff to organize a call with AFT and NEA the next morning prior to the guidance being released.[1745]

According to emails reviewed by the Select Subcommittee, on February 12, 2021, Dr. Walensky instructed Dr. Walke to incorporate the AFT's language into the Operational Strategy, even though the Operational Strategy had already been previewed for the media.[1746] Specifically, Dr. Walensky emailed "[a]re we able to add the bolded line below, bolding is mine." Dr. Walke replied, "[y]es, will work with team."[1747]

Accordingly, AFT Edit 2 also made it into the final Operational Strategy largely unchanged.

[1741] *See*, Nedrow TI, *supra* note 1666.
[1742] *Id.*
[1743] E-Mail from Christopher Jones, Ctr. for Disease Control and Prevention, to Randi Weingarten, Am. Fed. of Teachers, *et. al*. (Feb. 11, 2021, 5:58 PM).
[1744] E-Mail from Donna Harris-Aikens, Dep't of Edu., to Randi Weingarten, Am. Fed. of Teachers (Feb. 11, 2021, 7:43 PM)
[1745] *Id.*
[1746] E-Mail from Walke, COVID-19 Incident Manager, U.S. Ctrs. For Disease Control & Prevention, to Dr. Rochelle Walensky, Dir. U.S. Ctrs. For Disease Control & Prevention (Feb. 12, 2021); Trevor Hunnicutt, *U.S. CDC Recommends Schools Reopen With Masks and Rigid Health Protocols,* REUTERS (Feb. 12, 2021).
[1747] E-Mail from Walke (Feb. 12, 2021).

AFT PROPOSED LANGUAGE "AFT EDIT 2"	OPERATIONAL STRATEGY FINAL VERSION
In the event high-community transmission results from a new variant of SARS-CoV-2, a new update of these guidelines may be necessary.	In the event of increased levels of community transmission resulting from a variant of SARS-CoV-2, updates to this guidance may be necessary.

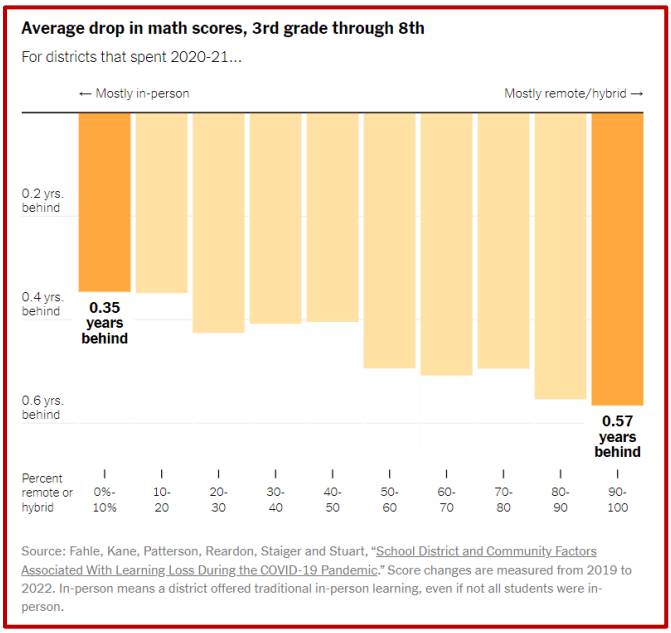
III. The Harmful Impacts from School Closures

The decision to close schools had predictable, but disastrous consequences for students' academics and mental and physical health. While the full scope of negative consequences of school closures is likely incalculable, certain adverse effects are documented.

The evidence makes it clear that any public health response that warrants closing schools should face the highest levels of scrutiny. School closure policy should be informed by science and data, not fear and politics.

FINDING:	Pandemic-era School Closures Adversely Impacted Academic Performance that Will Continue for Years.

There has been a significant decline in students' academic performance because of pandemic-era school closure policies. Standardized test scores show that children lost decades worth of academic progress.[1748] The performance of 9-year-olds in math and reading declined to levels recorded two decades ago, and the average composite score for the ACT by high school graduates dropped below 20 for the first time since 1991.[1749] The students whose classes were less disrupted in the 2020-2021 school year lost about 20 percent of math learning compared to losses of 50 percent for students who did not have access to in-person instruction.[1750]


Average drop in math scores, 3rd grade through 8th
For districts that spent 2020-21...
← Mostly in-person
Mostly remote/hybrid →
0.2 yrs. behind
0.4 yrs. behind
0.6 yrs. behind
0.35 years behind
0.57 years behind
Percent remote or hybrid
0%-10%
10-20
20-30
30-40
40-50
50-60
60-70
70-80
80-90
90-100
Source: Fahle, Kane, Patterson, Reardon, Staiger and Stuart, "School District and Community Factors Associated With Learning Loss During the COVID-19 Pandemic." Score changes are measured from 2019 to 2022. In-person means a district offered traditional in-person learning, even if not all students were in-person.

[1748] Sarah Mervosh, *The Pandemic Erased Two Decades of Progress in Math and Reading*, THE N.Y. TIMES, (Sep. 1, 2022); Cheyanne Mumphrey, *ACT test scores drop to lowest in 30 years in pandemic slide*, ASSOCIATED PRESS (Oct. 12, 2022); Rebecca Jack, *et. al.*, *Pandemic Schooling Mode and Student Test Scores: Evidence from U.S. School Districts*, NBER WORKING PAPER SERIES (Apr. 26, 2022).
[1749] *Id.*
[1750] Leonhardt, David, *Not Good for Learning*, THE N.Y. TIMES (May 5, 2022).

Disturbingly, these declines were the most significant among low-income children and children from racial minorities.[1751] Schools in urban areas attended by low income and minority children were kept closed longer.[1752] Accordingly, Black and Latino students and low-income students fell further behind in learning than their peers.[1753]

The effects of pandemic-era school closure policies continue to impact students today. Students are not rebounding from the effect of the school closure policies: "Analyses of student test scores have repeatedly shown severe declines in academic achievement… accelerating student learning… is notoriously challenging."[1754] More troubling than students' inability to "catch up" with where they should be academically, though, is the fact that the problem is growing worse: "except for the youngest learners, students are progressing more slowly than their pre-pandemic peers – furthering widening academic gaps."[1755]

Many students never returned to public schools following prolonged pandemic-era school closures. While many students were enrolled in private schools,[1756] an estimated 230,000 students have simply "disappeared" from public schools since the pandemic closed schools.[1757]

According to Eric Hanushek, an economist at the Hoover Institution, pandemic-era students could lose an estimated $70,000 in lifetime income.[1758] These losses are estimated to be two to nine percent of lifetime earnings, depending on the state they live and the severity of school closures.[1759] As a result of a lower-skilled workforce, states are estimated to have 0.6 to 2.9 percent lower gross domestic product (GDP), as total societal losses could amount to $28 trillion over the century.[1760]

The fact that these children had the poor fortune of being children during a global pandemic has only been exacerbated by pandemic-era school closure policies. While initial government action erring on the side of caution in response to a novel pandemic is a sensible course of action, the failure to adjust to current data and understanding of COVID-19 cost these students valuable time inside of the classroom. Again, the complete scope of academic loss is

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[1751] *Id*.
[1752] *Id*.
[1753] *Id*.
[1754] Sarah Schwartz, *Students Aren't Rebounding From the Academic Effects of the Pandemic*, EDUCATION WEEK (July 11, 2023).
[1755] *Id.*
[1756] Jason L. Riley, *School Choice Made Big Gains During the Covid Pandemic*, THE WALL STREET JOURNAL (Nov. 22, 2022).
[1757] Bianca Vazquez Toness & Sharon Lurye, *Thousands of kids are missing from school. Where did they go?,* ASSOCIATED PRESS (Feb. 9, 2023); Thomas S. Dee, *Where the Kids Went: Nonpublic Schooling and Demographic Change during the Pandemic Exodus from Public Schools,* URBAN (Feb. 9, 2023).
[1758] Emily Baumgaertner, *Students Lost One-Third of a School Year to Pandemic, Study Finds*, THE N.Y. TIMES (Jan. 30, 2023; Eric A. Hanushek, *The Economic Cost of the Pandemic: State by State*, HOOVER EDUCATION SUCCESS INITIATIVE (2023).
[1759] *Id*.
[1760] *Id*.

impossible to measure. However, the data is clear enough to display that these policies had a significant adverse impact education

FINDING:	School Closures Significantly Contributed to Increased Instances of Mental and Behavioral Health Issues.

During the pandemic, rates of psychological distress among students, including anxiety, depression, and other mental health problems, significantly increased. Among other things, these mental health issues can be attributed to pandemic-era school closure policies, which isolated students from their peers, restricted sports and other extracurricular activities, and led to excessive screen time.[1761]

Initially, school closures primarily impacted students with pre-existing mental conditions. Many of these students lost access to critical mental health resources usually available through school.[1762] As the pandemic progressed, however, these mental health issues broadened to affect all students.[1763]

In 2021, according to CDC data, 37 percent of high school students reported experiencing poor mental health during the COVID-19 pandemic, and 44 percent reported they persistently felt sad or hopeless during the past year compared to 36.7 percent in 2019.[1764]

Suicide attempts increased sharply for adolescents with suicide attempts by 12- to 17-year-old girls rising 51 percent from early 2019 to early 2021.[1765]

A 2021 NIH study acknowledged that COVID-19 related disruptions to everyday life led to increases in anxiety and depression, which in turn led teens to self-medicate.[1766] As a result, the U.S. Surgeon General issued a warning, and the American Academy of Pediatrics declared a national state of emergency in children's mental health.[1767]

[1761] Tracy Hoeg, *et al.*, *Our next national priority should be to reopen all America's schools for full time in-person learning*, THE HILL (Mar. 20, 2021).
[1762] Joyce Lee, *Mental health effects of school closures during COVID-19*, THE LANCET (June 2020).
[1763] Tracy Hoeg, *et al.*, *Our next national priority should be to reopen all America's schools for full time in-person learning*, THE HILL (Mar. 20, 2021).
[1764] Erica Green, *Administration Offers Guidance to Schools as They Shut Down on Their Own*, THE N.Y. TIMES, (Mar. 13, 2020)*; See,* News Release, U.S. Ctrs. for Disease Control & Prevention, New CDC data illuminate youth mental health threats during the COVID-19 pandemic (Mar. 31, 2022).
[1765] *Id*.
[1766] Chopra, Deepti, *et al*., *Prevalence of self-reported anxiety and self-medication among upper and middle socioeconomic strata amidst COVID-19 pandemic*, JOURNAL OF EDUCATION AND HEALTH PROMOTION (Feb. 27, 2021).
[1767] Press Release, U.S. Surgeon General Issues Advisory on Youth Mental Health Crisis Further Exposed by COVID-19 Pandemic, U.S. Dep't of Health & Human Servs. (Dec.7, 2021); Press Release, American Academy of Pediatrics, AAP-AACAP-CHA Declaration of a National Emergency in Child and Adolescent Mental Health (Oct. 19, 2021).

Reports have shown that for "children between the ages of 11 and 17, additional weeks of home schooling in the early months of the pandemic correlated with worsening mental health measures."[1768] This study found that "younger children were more adversely affected," a troubling, yet again predictable, consequence of the isolation of the most vulnerable of the population.[1769]

The data are clear that prologued school closures had an adverse effect on the mental health of students. Science shows that the prolonged closures had negative effects. When science showed that the shutdowns were no longer necessary, policies should have acted to mitigate the harm done.

FINDING:	School Closures Made an Already Alarming Trend in Declining Physical Health Worse.

Pandemic-era school closure policies not only affected academics and students' mental health, but also had negative consequences on their physical health. As with students' academic performance and mental health, the adverse physical effects were predictable; prolonged school closures had a measured impact on students' physical health.[1770] Among other things, in-person schooling provides students with access to nutritious lunches and regularly scheduled physical activity, including exercise classes, sports, and other extracurricular activities.[1771]

As a result of school closures, physical activity significantly decreased and sedentary behavior, including but not limited to watching television, playing video games, and using the computer, increased.[1772]

Accordingly, the rate of BMI increases for children ages 2-19 approximately doubled from pre-pandemic rates.[1773] The number of new cases of Type 2 diabetes among children during the first year of the pandemic increased 182 percent from pre-pandemic levels.[1774] These increases disproportionately affected black youth.[1775]

[1768] Gretchen Vogel, *Pandemic school closures were especially hard on the mental health of younger, more vulnerable children*, SCIENCE.ORG (Aug. 18, 2023); *citing* Christina Felfe, *et al.*, *The youth mental health crisis: Quasi-experimental evidence on the role of school closures*, SCIENCE ADVANCES (Aug. 18, 2023).
[1769] *Id.*
[1770] Andrew Rundle, *et al.*, *COVID-19—Related School Closings and Risk of Weight Gain Among Children*, THE OBESITY SOCIETY, (Mar. 30, 2020).
[1771] *Id.*; Jennifer Nuzzo, *We Don't Need to Close Schools to Fight the Coronavirus*, THE N.Y. TIMES (Mar. 10, 2020).
[1772] Paulo Puccinelli, *et al.*, *Reduced level of physical activity during COVID-19 pandemic is associated with depression and anxiety levels: an internet-based survey*, BMC PUBLIC HEALTH (Mar. 1, 2021); D.S. Burstein, *Cardiopulmonary Exercise Performance in the Pediatric and Young Adult Population Before and During the COVID-19 Pandemic*, PEDIATRIC CARDIOLOGY (May 3, 2022).
[1773] Press Release, Ctrs. For Disease Control and Prevention, *Longitudinal Trends in Body Mass Index Before and During the COVID-19 Pandemic Among Persons Aged 2-19 Years – United States, 2018-2020*, MMWR Morb Mortal Wkly Rep, (Sep. 17, 2021).
[1774] Brynn Marks, *et al.*, *Increase in the Diagnosis and Severity of Presentation of Pediatric Type 1 and Type 2 Diabetes during the COVID-19 Pandemic*, HORMONE RESEARCH IN PEDIATRICS (Sept. 24, 2021).
[1775] *Id.*

It should come as no shock that isolation is not healthy, in any respect, for people—let alone children. The results of prolonged school closures have exacerbated physical health issues while simultaneously hampering activities that would otherwise mitigate those issues, such as communal sport and exercise, and a healthy diet.

Generally, the immune system benefits from physical activity. It is well established that accelerated weight gain and obesity can cause long-term metabolic changes that increase the risk of heart disease, cancer, mental health issues, and diabetes, as well as complications with subsequent morbidity and premature mortality, for children.[1776] During the pandemic, studies showed that obese children were more likely to suffer severe respiratory complications as a result of COVID-19.[1777]

Yet again, warnings from scientists, and the common sense understanding that isolation is bad for a child, were largely unheeded by policymakers. A February 2021 preprint of a study (finally published in January 2022) found negative health impact on children due to school closures, and warned of already troubling data that would only compound if closures continued:

> Available data are short-term and longer-term harms are likely to be magnified by further school closures. Data are urgently needed on longer-term impacts using strong research designs, particularly amongst vulnerable groups. These findings are important for policymakers seeking to balance the risks of transmission through school-aged children with the harms of closing schools.[1778]

Despite the evidence of incredibly low morbidity among children, students were not given the benefit of balanced policy.

[1776] Sandeep Tripathi, *et al., The Impact of Obesity on Disease Severity and Outcomes Among Hospitalized Children With COVID-19,* AMERICAN ACADEMY OF PEDIATRICS (Nov. 1, 2021); Lyudmyla Kompaniyets, *et al., Underlying Medical Conditions Associated With Severe COVID-19 Illness Among Children*, JAMA NETWORK (June 7, 2021).
[1777] Brynn Marks, *et al.*, *Increase in the Diagnosis and Severity of Presentation of Pediatric Type 1 and Type 2 Diabetes during the COVID-19 Pandemic*, HORMONE RESEARCH IN PEDIATRICS (Sept. 24, 2021).
[1778] Russell Viner, *et al., Impacts of school closures on physical and mental health of children and young people: a systematic review*, MEDRXIV (Feb. 12, 2021); Russell Viner, *et al., School Closures During Social Lockdown and Mental Health, Health Behaviors, and Well-being Among Children and Adolescents During the First COVID-19 Wave*, JAMA PEDIATRICS (Jan. 18, 2022).

Cooperation By the Executive Branch and Others with Congress, the Inspectors General, the Government Accountability Office, and Others in Connection with Oversight of the Preparedness for and Response to the Coronavirus Pandemic

I. The Biden Administration's U.S. Department of Health and Human Services Obstructed the Select Subcommittee's Investigation

The Executive Branch largely coordinated the U.S. government's pandemic response, specifically through departments like HHS and its various sub-agencies. Therefore, the Select Subcommittee, to properly fulfill its Constitutionally mandated oversight and legislative responsibilities, requested documents and information from HHS and its sub-agencies. This included both the production of underlying documents and testimony from numerous agency officials.

During the course of the Select Subcommittee's investigation, HHS sought to impede and slow-roll requests for documents vital to our investigation. HHS also repeatedly hampered the Select Subcommittee's access to and interviews of key witnesses. In fact, based on statements from Ms. Egorin, it appears HHS intentionally under-resourced its component that responds to legislative oversight requests as a pretextual excuse regarding why they cannot timely comply with requests from Congress.[1779] HHS did not specifically refute this point in subsequent letters.[1780] Furthermore, Congresswoman Jill Tokuda (D-HI) offered Ms. Egorin an opportunity to refute intentionally under-resourcing her legislation office during testimony before the subcommittee but chose not to refute this point.[1781]

> **The Honorable Melanie Egorin (January 31, 2024)**
>
> Q. Thank you, Mr. Chair. Before I get started I would like to take a moment to clear some things up for the record. We have heard accusations that the Department has intentionally devoted minimal resources towards handling congressional oversight and inquiries, but let's also remind people that every day your primary responsibility is the health and wellness of 340 million Americans, keeping them alive and well. Assistant Secretary Egorin, would you like to clarify anything briefly regarding this claim?

[1779] Letter from Hon. Brad Wenstrup, D.P.M., *et. al.,* Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, to Hon. Xavier Becerra, Sec'y, U.S. Dept. of Health & Human Servs., at 7 (Nov. 2, 2023).

[1780] *See e.g.,* Letter from Hon. Melanie Anne Egorin, Ass't Sec'y for Legislation, U.S. Dept. of Health & Human Servs., to Hon. Brad Wenstrup, *et. al*., Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability (Nov. 8, 2023); Letter from Hon. Samuel Bagenstos, Gen. Counsel, U.S. Dept. of Health & Human Servs., to Hon. Brad Wenstrup, D.P.M., *et. al.,* Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability (Nov. 9, 2023).

[1781] Overseeing the Department of Health and Human Services' Compliance with Congress: Hearing Before the Select Subcomm. on the Coronavirus Pandemic, 118th Cong. 2, at 29 (Jan. 31, 2024) [hereinafter "Overseeing HHS Hearing"].

A.	I want to just acknowledge the mission of the Department is to make sure we are taking care of the welfare of the American people and that that is a very broad set of activities.

FINDING:	The Biden Administration's U.S. Department of Health and Human Services Deliberately Obfuscated Evidence that Could Incriminate or Embarrass Senior Public Health Officials.

The volume of HHS' production of documents is completely unsatisfactory. The Select Subcommittee's requests for records concerning the origins of COVID-19 and funding of gain of function research is illustrative of this conclusion. During its two-year investigation, the Select Subcommittee made repeated requests for records pertaining to the origins of COVID-19 and the U.S. funding of gain of function research. To limit HHS' search efforts, the Select Subcommittee identified specific employees and search terms.[1782] In the past 22 months, during which it was supposed to search multiple employees' email accounts using a long list of search terms, HHS only produced 14,799 pages of documents that it claims pertain to the origins of COVID-19 or gain of function research. The vast majority of these documents contained some form of redaction or were entirely already publicly available. In contrast, a FOIA search of only Dr. Morens' official email account for only documents between himself and Dr. Daszak or using the terms "Daszac" [sic] or "gain-of-function" yielded more than 30,000 pages of documents.[1783]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1782] *See e.g.,* Letter from Hon. Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, *et. al*., to Hon. Xavier Becerra, Sec'y, U.S. Dept. of Health & Human Servs., at Appendices II & III. (Nov. 2, 2023).

[1783] Letter from Hon. Brad Wenstrup, D.P.M., *et. al.,* Chairman, Select Subcomm. on the Coronavirus Pandemic, *et. al*., to David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (May 8, 2024).

From: Travis Miller Personal Information
Sent: Thursday, September 16, 2021 2:53 PM
To: Schofield, Robin (NIH/NIAID) [E] Personal Information
Subject: Re: Question Regarding FOIA Request #57014

Hi Robin,

I'll agree to accept the e-mails between Dr. Morens and Daszac.

Also, for the purposes of limiting the scope, I'm OK to limit the "gain of function" search request from January 1, 2020 through March 31, 2020.

Thanks,

Travis

On Thu, Sep 16, 2021 at 1:00 PM Schofield, Robin (NIH/NIAID) [E] Personal Information wrote:

> Good afternoon Mr. Miller,
>
> I am contacting you regarding your recent FOIA request for documents from the e-mailboxes of Dr. David Morens to or from Dr. Peter Daszac or containing the terms Daszac or "gain of function". Our e-Discovery unit has run the searches and the results are over 30,000 pages. The NIAID and NIH FOIA Offices are inundated with requests at this time, and as we have previously discussed, you will receive responsive documents in a more timely manner if you can target your request to a reasonable volume. Would you be willing to amend your request to exclude the second part and agree to accept emails between Dr. Morens and Dr. Daszac? We are already processing several related requests for documents of other members of Dr. Morens' office for you so once you receive some of those documents, you would be able to possibly come in with a new, more targeted request if you were still interested in more documents.
>
> Please advise.
>
> Thank you.

In sum, the Select Subcommittee requested documents from 12 custodians that were responsive to questions regarding the origins of COVID-19, the work of EcoHealth, interactions with the WIV, and gain-of-function research. This request resulted in HHS producing 14,799 pages of documents. However, one FOIA search of one custodian for only two search terms resulted in 30,000 pages of documents. These facts support that HHS obstructed the Select Subcommittee.

The substance and quality of HHS' production of documents is unacceptable. For example, a document production on March 11, 2024 consisted of 413 pages of documents. All but 37 pages—about nine percent—of that production are printed media stories that were part of an NIH officials' regular morning news distribution list. Many other productions contained similar public documents. At a hearing in January 2024, the Select Subcommittee unequivocally told HHS that it had produced documents that are simply unrelated to our requests—"You [HHS] have produced documents that are not relevant to our requests or hundreds of pages of news articles. This is unacceptable...."[1784] Yet, HHS continued to produce these irrelevant documents. These productions demonstrate that HHS created an appearance of compliance by increasing its production page count by feeding the Select Subcommittee hundreds of pages of nonresponsive, irrelevant, and public documents.

The pace of HHS' production of documents has been abysmal. Focusing on its production of documents relevant to the origins of COVID-19, HHS' pace of production has slowed over time. In the months prior to November 2023, HHS routinely produced three or even four productions per month.[1785] Since November 2023, HHS is averaging just two productions per month and has not made a single production since September 6, 2024.[1786]

HHS' productions are incomplete or overly redacted. HHS produced to the Select Subcommittee many documents more heavily redacted than those same documents produced via FOIA.[1787] FOIA explicitly does not apply to Congressional requests. According to the law itself, "[t]his section is not authority to withhold information from congress."[1788] Additionally, the accompanying bill report states, "[f]urther, it is made clear that, because this section only refers to the public's right to know, it cannot, therefore be backhandedly construed as authorizing the withholding of information from the Congress, the collective representative of the public."[1789]

For example, the first document below was produced by HHS to the Select Subcommittee on June 26, 2023 and the second document was produced to a FOIA requester in June 2021—HHS redacted more information produced to Congress than it did to the FOIA requester.

[1784] Overseeing HHS Hearing, *supra,* note 1781, at 3 (Statement of Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability).
[1785] Letter Hon. Melanie Egorin, Ph.D., Ass't Sec'y for Legislation, U.S. Dept. of Health & Human Servs, to Hon. Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability *et. al.,* at 7-8 (Mar. 1, 2024).
[1786] *Id.* at 9-10.
[1787] *See e.g.,* SSCP_NIH002640 – 2967 where all names of individuals are redacted versus documents obtained via FOIA by Judicial Watch, Inc. where names are, largely, unredacted.
[1788] 5 U.S.C. Sec. 552(d).
[1789] S. Rep. No. 813 (Oct. 4, 1965).

From: Chen, Ping (NIH/NIAID) [E]
Sent: Mon, 11 Aug 2014 09:30:40 -0400
To: [redacted] (NIH/NIAID) [E]; [redacted] (NIH/NIAID) [E]; [redacted] (NIH/NIAID) [E]
Subject: Fw: Contact to Wuhan Institute of Virology
Importance: High

FYI.
The message from [redacted] of UTMB from him we got the contacts for WIV.

Ping

----- Original Message -----
From: [redacted]@UTMB.EDU]
Sent: Friday, August 08, 2014 09:24 AM Eastern Standard Time
To: Chen, Ping (NIH/NIAID) [E]
Cc: [redacted] <[redacted]@UTMB.EDU>; [redacted] <[redacted]@UTMB.EDU>
Subject: RE: Contact to Wuhan Institute of Virology

Ping,

As indicated, we have a post doc from the Chinese Academy of Sciences, Dr [redacted] working in our lab and undergoing training for both research in our BSL4 facilities as well as orientation to the maintenance and operations of a BSL4 facility. She is part of a larger initiative I've been developing to form long-term scientific and technical collaborations with the new BSL4 laboratory now nearing completion in Wuhan, which will be under the direction of Dr [redacted] I have met with Dr [redacted] repeatedly while in Wuhan and he has expressed interest in visiting the GNL sometime soon, which I welcome. [redacted] and her mentor, Dr [redacted] will likely be traveling to Wuhan sometime in the next 6 months to explore collaborative research activities that they might jointly pursue when [redacted] returns to Wuhan. On her return, she will likely also be involved in the oversight of laboratory operations based on her experience gained here. All of this to say that we are already attempting to build the kind of partnership that I think is envisioned under the GHSA. I hope that in your dealings with the scientists from Wuhan, and especially Dr [redacted] that you will keep our efforts in mind and look for opportunities where our partnership might be strengthened under the GHSA. Clearly considering support for the joint studies we are attempting to develop would be a potential early win for all of us. We have invested considerably in our partnership with the CAS in Wuhan and we are anxious to ensure its long-term success.

Thanks, [redacted]

[redacted]
Director
Galveston National Laboratory
University of Texas Medical Branch
Galveston, TX 77555-0610
[redacted]
[redacted]@utmb.edu

From: Chen, Ping (NIH/NIAID) [E]
Sent: Mon, 11 Aug 2014 09:30:40 -0400
To: Bernabe, Gayle (NIH/NIAID) [E];Handley, Gray (NIH/NIAID) [E];Meegan, James (NIH/NIAID) [E]
Subject: Fw: Contact to Wuhan Institute of Virology
Importance: High

FYI.
The message from LeDuc of UTMB from him we got the contacts for WIV.

Ping

----- Original Message -----
From: LeDuc, James W. [mailto:jwleduc@UTMB.EDU]
Sent: Friday, August 08, 2014 09:24 AM Eastern Standard Time
To: Chen, Ping (NIH/NIAID) [E]
Cc: Xia, Han <haxia@UTMB.EDU>; Bente, Dennis A. <dabente@UTMB.EDU>
Subject: RE: Contact to Wuhan Institute of Virology

Ping,

As indicated, we have a post doc from the Chinese Academy of Sciences, Dr Han Xia working in our lab and undergoing training for both research in our BSL4 facilities as well as orientation to the maintenance and operations of a BSL4 facility. She is part of a larger initiative I've been developing to form long-term scientific and technical collaborations with the new BSL4 laboratory now nearing completion in Wuhan, which will be under the direction of Dr Yuan Zhiming. I have met with Dr Zhiming repeatedly while in Wuhan and he has expressed interest in visiting the GNL sometime soon, which I welcome. Han Xia and her mentor, Dr Dennis Bente, will likely be traveling to Wuhan sometime in the next 6 months to explore collaborative research activities that they might jointly pursue when Han returns to Wuhan. On her return, she will likely also be involved in the oversight of laboratory operations based on her experience gained here. All of this to say that we are already attempting to build the kind of partnership that I think is envisioned under the GHSA. I hope that in your dealings with the scientists from Wuhan, and especially Dr Zhiming, that you will keep our efforts in mind and look for opportunities where our partnership might be strengthened under the GHSA. Clearly considering support for the joint studies we are attempting to develop would be a potential early win for all of us. We have invested considerably in our partnership with the CAS in Wuhan and we are anxious to ensure its long-term success.

Thanks, Jim

James W. Le Duc, Ph.D.
Director
Galveston National Laboratory
University of Texas Medical Branch
Galveston, TX 77555-0610
(t) 409-266-6500
(f) 409-266-6810
jwleduc@utmb.edu

In this one example, HHS redacted the names of federal government employees, non-governmental employees, and foreign nationals—including members of the CCP—under the guise of a "concerning escalation of threats and harassment, particularly towards public health professionals and scientists."[1790] In response, the Select Subcommittee asked, "[i]s the

[1790] E-Mail from Staff, U.S. Dept. of Health & Human Servs., to Staff, Select Subcomm. on the Coronavirus Pandemic (June 27, 2023).

Department tracking a rise in threats since its last production on June 8? Moreover, how does the Department know that the foreign nationals living in China whose names are redacted have received threats? Is the Department in personal contact with these individuals?"[1791] HHS failed to answer these questions.

Finally, HHS frequently made no effort to hide their intentional noncompliance. When the Select Subcommittee questioned the paucity of documents produced and requested HHS' searches, HHS refused to explain its methodology regarding how it conducted its searches.[1792] When the Select Subcommittee questioned why HHS was not complying with its requests, it sought to interview Ms. Egorin on September 28, 2023.[1793] While never specifically refusing to appear to be interviewed, HHS staff twice postponed the interview for a total of two weeks due to illness. During many e-mails and phone calls, HHS staff never stated Ms. Egorin would refuse to comply with the interview. On the eve of the scheduled interview, HHS sent a letter in which it cravenly stated that the interview was unwarranted.

FINDING: The Biden Administration's U.S. Department of Health and Human Services Unreasonably and Possibly Illegally Limited Access to Key Witnesses.

First, HHS unreasonably delayed scheduling interviews. On February 13, 2023, the Select Subcommittee initially requested interviews with HHS employees regarding the origins of COVID-19 and gain of function research.[1794] It took two follow-up letters and numerous emails and phone calls before the Select Subcommittee conducted its first interview of an HHS employee pertaining to the origins of COVID-19 on November 2, 2023.

When HHS eventually complied with and facilitated its employees for interviews with Select Subcommittee, the Department sought to unreasonably limit their testimony. There are two illustrative examples of this obstruction.

First, for the Select Subcommittee's interview with Dr. Lauer—and many subsequent HHS officials—HHS instructed Dr. Lauer to only answer questions regarding his "review, management, and oversight of NIH grant #R01AI110964 through April 26, 2023." This instruction prohibited Dr. Lauer from speaking about the renegotiation and reinstatement of EcoHealth's grant—a primary line of inquiry of the Select Subcommittee.[1795]

[1791] E-Mail from Select Subcomm. Staff to Staff, U.S. Dept. of Health & Human Servs. (June 27, 2023).
[1792] Letter from Hon. Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, *et. al.,* to Hon. Xavier Becerra, Sec'y, U.S. Dept. of Health & Human Servs. (Nov. 2, 2023).
[1793] *Id.*
[1794] Letter from Hon. Brad Wenstrup, *et. al.,* Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability (Feb. 13, 2023).
[1795] Letter from Hon. Melanie Egorin, Assistant Sec'y for Legislation, U.S. Dep't of Health & Human Servs, to Michael Lauer, M.D., Deputy Dir. For Extramural Research, Nat'l Insts. of Health (Nov. 1, 2023).

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

TO: Dr. Michael S. Lauer, MD, Deputy Director for Extramural Research, National Institutes of Health

FROM: Melanie Anne Egorin, Assistant Secretary for Legislation *Melanie Anne Egorin*

SUBJECT: Transcribed Interview Before the House Committee on Oversight and Accountability, the Committee on Energy and Commerce, and the Select Subcommittee on the Coronavirus Pandemic

DATE: November 1, 2023

It is my understanding that you will be participating in a transcribed interview on November 2, 2023, in your official capacity as the deputy director for extramural research at the National Institutes of Health (NIH). This interview is pursuant to a request from the House of Representatives Select Subcommittee on the Coronavirus Pandemic, the House Committee on Oversight and Accountability, and the House Committee on Energy and Commerce (the "Committees") in connection with letters sent to the Department on February 13, 2023, and September 14, 2023. The purpose of this memorandum is to provide you with guidance on the extent to which you are authorized to provide information to the Committees.

The letters requesting this interview sought information regarding the origins of the COVID-19 pandemic. As you know, the Department of Health and Human Services (HHS or Department) strives to cooperate with Congress and respond to its requests for information regarding our work to prevent and respond to public health emergencies.

To that end, you are authorized to respond to questions regarding your role as the deputy director for extramural research for NIH in the review, management, and oversight of NIH grant #R01AI110964 through April 26, 2023. Of course, you should be careful to testify as to those facts of which you have personal knowledge and to refrain from speculating as to matters of which you have no sure knowledge. If you have any questions regarding the scope of your authorization to discuss certain information, please consult with HHS counsel prior to disclosure of such information to the Committees.

You will be appearing before the Committees on a voluntary basis. The sole memorialization of the transcribed interview will be the written transcript, provided by the official reporter. The Department expects to have the opportunity to review a draft of the transcript and submit any errata, as appropriate.

Second, for the Select Subcommittee's first interview of Dr. Morens, HHS instructed Dr. Morens to only answer questions regarding his use of personal e-mail, not any substantive questions regarding the origins of COVID-19 or his work as Senior Scientific Advisor to Dr.

Fauci.[1796] The Select Subcommittee requested an interview with Dr. Morens even prior to discovering his use of personal e-mail.[1797] Further, it was clear the Select Subcommittee had questions for Dr. Morens regarding his involvement with or knowledge of the origins of COVID-19, gain of function research, and other areas articulated in the SSCP's mandate.[1798] On the eve of Dr. Morens' first interview, HHS instructed Dr. Morens to not provide "information about your work for NIAID."[1799]

[1796] Transcribed Interview of David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases (Dec. 29, 2023) [hereinafter "Morens TI 1"].
[1797] Letter from Hon. Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, *et al.,* to Hon. Xavier Becerra, Sec'y, U.S. Dept. of Health & Human Servs. (Feb. 13, 2023).
[1798] Letter from Hon. Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, *et. al.,* to Hon. Xavier Becerra, Sec'y, U.S. Dept. of Health & Human Servs. (Jun. 29, 2023).
[1799] Letter from Hon. Melanie Anne Egorin, Ass't Sec'y for Legislation, U.S. Dept. of Health & Human Servs., to Dr. David Morens, M.D., Senior Scientific Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Dec. 28, 2023).

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

TO: Dr. David M. Morens, M.D., Senior Scientific Advisor, Office of the Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health

FROM: Melanie Anne Egorin, Assistant Secretary for Legislation *Melanie Anne Egorin*

SUBJECT: Transcribed Interview Before the House Select Subcommittee on the Coronavirus Pandemic

DATE: December 28, 2023

It is my understanding that you will be participating in a transcribed interview on December 29, 2023, pursuant to a request from the House of Representatives Select Subcommittee on the Coronavirus Pandemic in connection with a letter sent to you on June 29, 2023, regarding certain communications you engaged in from personal accounts. The purpose of this memorandum is to provide you with guidance on the extent to which you are authorized to provide information to the select subcommittee in your capacity as an NIH employee.

Given that the subject matter of the select subcommittee's requests center on communications from your personal, rather than official NIH, accounts, it is the Department of Health and Human Services' understanding that you will not be providing information about your work for NIAID. If you have any questions regarding the scope of your authorization to discuss information pertaining to your official work, please consult with agency counsel prior to disclosure of such information to the select subcommittee.

These purported "authorization letters" not only obstructed the Select Subcommittee's investigation but are also questionably illegal. At the interview, HHS counsel attempted to persuade the Select Subcommittee that the letter to Dr. Morens was not directive nor mandatory in nature yet still instructed the Dr. Morens to not answer questions. Instructing a federal government employee to not comply with Congress is unacceptable and unlawful.

Dr. David Morens (December 29, 2023)

Q.	Thank you. Dr. Morens, before we get into the substance last night, I'm presuming you, Tim, and we received an authorization memo from HHS Assistant Secretary Egorin. I would like to introduce that as Exhibit 1.
HHS Counsel.	Do you have copies for Agency staff?

Q. I'll wait for it to get around.

Q. Did you receive this memo last night?

Dr. Morens. I did.

Q. Did counsel receive this memo last night?

Mr. Belevetz. Yes.

Q. I would like to state for the record that the Select Subcommittee did not and does not agree to the terms of this memo. Despite that, the operative paragraph reads: "Given that the subject matter of the Select Subcommittee's requests center on communications from your personal, rather than official NIH, accounts, it is the Department of Health and Human Services' understanding that you will not be providing information about your work for NIAID. If you have any questions regarding the scope of your authorization to discuss information pertaining to your official work, please consult with agency counsel prior to disclosure of such information to the Select Subcommittee." The premise that the Select Subcommittee's inquiry only involves your use of personal email is false. The letter sent to you by Chairman Wenstrup, in fact, cited emails sent from your official email and other documents through which you have knowledge regarding COVID origins. The Department knows this. Second, the Department cannot block you from providing testimony regarding your official work at NIAID or on COVID origins. The decision as to what testimony you give rests solely with you. The Department also knows this.

Q. I would like to introduce Majority Exhibit 2.

Q. While it is working its way around, I will identify it. At the bottom right side of the second column, this is Title 5, Section 7211 of the United States Code. It reads: "The right of employees, individually or collectively, to petition Congress or a Member of Congress, or to furnish information to either House of Congress, or to a committee or Member thereof,

	may not be interfered with or denied." Dr. Morens, the Department's authorization memo is attempting to obstruct this committee and attempting to interfere with your legal right to furnish information to Congress.
HHS Counsel.	Mitch, I'm going to object to your characterization of the authorization memo.
Q.	That's fine.[1800]

Dr. David Morens (December 29, 2023)

Q.	If this is legally binding on Dr. Morens, this is a crime. So it's either advisory and he can answer whatever questions we ask him, or HHS is taking the position that you can interfere with an employee's ability to talk to Congress.
HHS Counsel.	HHS does not take the position that we can interfere with an employee's ability to talk to Congress.
Q.	So then the scope of this authorization is, I guess, advisory to Dr. Morens?
HHS Counsel.	John, in the memo itself, it says, "The purpose of this memorandum is to provide you with guidance on the extent to which you are authorized to provide information to the Select Subcommittee in your capacity as an NIH employee." That's the purpose of the memorandum.
Q.	"If you have any questions regarding the scope of your authorization to discuss information pertaining to your official work, please consult with agency counsel prior to disclosure of such information to the Select Subcommittee." That sounds mandatory. And I guess the concern is particularly acute with Dr. Morens, because the previous ones have more or less been within the scope of, like, the February letters. But with Dr. Morens, we unfortunately have the situation where he isn't able to be represented by

[1800] Morens TI 1, *supra* note 1796, at 10-11.

	agency counsel, but he's retained counsel on his own dime, so there's a divergence of legal interests between Dr. Morens and the Department. I might also add that the Department is going to be the one that's adjudicating the NARA, the records retention issues. And so the impression that this memo gives is that you guys are essentially precluding him from speaking to stuff that's relevant to the origins investigation uniquely to him. But you also have a unique degree of leverage over him because he is under investigation, like any I don't know the probability of this, but, like, technically, he's at risk of being separated from federal service, he's at risk of having portions of his pension forfeited for these violations. Those are adjudications of, like, OGC HHS are going to be involved in making. And you're now telling him, you can't talk about your official work at NIAID when every other NIAID employee that we've done a voluntary interview with has been allowed to talk about that.
HHS Counsel.	John, this memorandum is separate and apart from any internal personnel process that might be happening. To be clear, it is not any kind of compulsion or threat that there will be adverse employment consequences if he does not abide by the terms of it. That is not the case.
Q.	So this is purely advisory? We can ask him questions like we have every other NIAID official?
HHS Counsel.	You can ask him questions as you would any other NIAID official. We will instruct him to limit his responses to his personal, non official activities. He, as a witness, is free to respond as he sees fit.[1801]

Despite HHS' position that Dr. Morens was free to answer questions regardless of instruction otherwise, Dr. Morens interpreted these instructions as binding and informed the Select Subcommittee he would not answer questions if instructed.[1802]

In sum, during two years of interaction with the subcommittee HHS has proven itself to be thoroughly disingenuous, unreliable, and cowardly in responding to oversight requests.

[1801] Morens TI 1, *supra* note 1796, at 13-15.
[1802] *See generally*, Morens TI 1, *supra* note 1796,

II. EcoHealth Alliance, Inc. and Dr. Peter Daszak Obstructed the Select Subcommittee's Investigation and Misled the Public

FINDING: EcoHealth Alliance, Inc. Obstructed a Congressional Investigation

On February 13, 20223, the Select Subcommittee first requested documents from Dr. Daszak and EcoHealth.[1803] Since, Dr. Daszak has attempted to obstruct the Select Subcommittee's investigation. Maybe most illustrative of this is that, according to Dr. Daszak, his goal of the May 1, 2024 public hearing before the Select Subcommittee was to "respond in a way that minimizes damage to EHA as much as possible." This conspicuously is not the same as telling the truth.

Some examples of Dr. Daszak's and EcoHealth's obstruction include:

1. As a preliminary matter, before the Select Subcommittee intervened, Dr. Daszak was searching, collecting, and producing documents and communications himself.[1804] This provides the opportunity for the subject of an investigation to either delete, ignore, or alter evidence. This is wholly inappropriate. As discussed, the Select Subcommittee has evidence that Dr. Daszak did, in fact, doctor documents he released to the public.

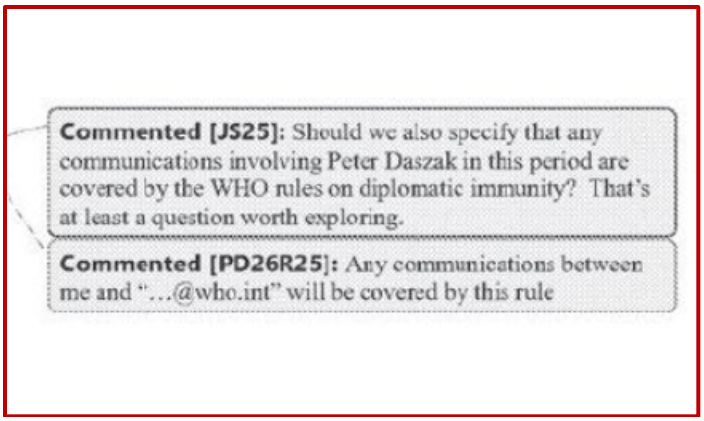
From: Peter Daszak [redacted]
Sent: Saturday, May 4, 2024 2:33 PM
To: Jeff Sturchio [redacted] Aleksei Chmura [redacted]
Subject: Strategy re. allegations from my public hearing.
Importance: High

Jeff – I'm thinking carefully about your suggestions, and the ideas from our call yesterday re. the wildlife trade idea etc.. Here are some initial thoughts that we can delve into further over the next few days:

The SSCP is not allowing us to respond to the allegations live, and is now trying to prevent us responding publicly. I'll fill you in by phone, but both D & R counsels met (R was in NYC, D on the phone) with our lawyers and are insisting that our lawyers now conduct all the email trawls they've requested previously. They cite an email from me to Jerry cc'd to David about 2 wks ago that they believe shows I'm trying to slow down production. What this means is now days of work going through thousands of emails to rapidly redact any privileged information and hand over. They said they will be releasing other emails in coming days. This means we'll always be on the back foot in any response

2. In response to the Select Subcommittee's request for documents and communications between Dr. Daszak and Dr. Marion Koopmans, a member of the WHO origins investigation, Dr. Daszak planned to obstruct the Select Subcommittee by claiming "diplomatic immunity" and "WHO privacy rules."[1805]

[1803] Letter from Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, *et. al*., to Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc. (Feb. 13, 2023).
[1804] E-Mail from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Dr. Jeffrey Sturchio, Consultant (May 4, 2024, 2:33 PM).
[1805] E-Mail from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Dr. Jeffrey Sturchio, Consultant (May 13, 2024, 2:43 AM).


Commented [JS25]: Should we also specify that any communications involving Peter Daszak in this period are covered by the WHO rules on diplomatic immunity? That's at least a question worth exploring.
Commented [PD26R25]: Any communications between me and "…@who.int" will be covered by this rule

3. In preparation for Dr. Daszak's public hearing on May 1, 2024, his consultant suggested Dr. Daszak respond in a "slow, deliberate cadence" and "with agonizingly slow delivery." Dr. Daszak responded, "I like both of these."

[REMAINDER OF PAGE INTENTIONALLY BLANK]

Message

From: Peter Daszak [redacted]
Sent: 5/1/2024 1:34:48 AM
To: Jeffrey Sturchio [redacted] Aleksei Chmura [redacted] John Feigelson [redacted] Porter DeLaney [redacted]
Subject: RE: Politico piece on USRTK today - with some good comments by Goldstein on how dishoest and destructive their "investigative journalism" has been

I like both of those

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: +1-212-380-4474
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Jeffrey Sturchio [redacted]
Sent: Tuesday, April 30, 2024 8:46 PM
To: Peter Daszak [redacted] Aleksei Chmura [redacted] John Feigelson [redacted] Porter DeLaney [redacted]
Subject: RE: Politico piece on USRTK today - with some good comments by Goldstein on how dishoest and destructive their "investigative journalism" has been

Peter: At some point, you should make that clear – not necessarily tomorrow, but in follow-up interviews and statements.

One of my long-time colleagues in strategic communications (😊) offered another approach you can use tomorrow, which he calls the "Finnish response." Imagine

you're a Finnish scientist asked to respond to a complex technical question. (This works best if you use a Finnish accent, or a reasonable facsimile.) Your response, in a slow, deliberate cadence is to say: "Thank you, Congressman, for that very important and interesting question. We have published at least 96 papers on this topic. To answer your question adequately, I really need to start at the beginning. In the first paper, we found X….." [Then repeat, with agonizingly slow delivery, through as many of the 96 papers as you can before the questioner begins to snore – or gets so agitated he cuts you off….] At that point, you say, "But Congressman, I am trying to answer your question – to do so appropriately requires me to provide this background…." You can keep this one in your back pocket as well!

As ever,
Jeff

4. On April 26, 2024, after the Select Subcommittee threatened to subpoena EcoHealth for documents, Dr. Daszak wrote, "[o]nce they write to us with issues on our production, we'll rapidly produce more and try to head this off at the pass."[1806] Dr. Daszak stated that he was withholding documents and then, once the Select Subcommittee threatened a subpoena, decided to produce more.

Message

From: Peter Daszak [redacted]
Sent: 4/26/2024 5:42:57 PM
To: [redacted] Jeffrey Sturchio [redacted] Aleksei Chmura
CC: [redacted]
Subject: RE: Likely SSCP subpoena today?

Completely agree with everything you're saying.

Once they write to us with issues on our production, we'll rapidly produce more and try to head this off at the pass.

Re. Jon Epstein communicating with David Morens, I believe he would likely be one of 4 or 5 max at ecohealth who would have reason to speak with David. I think his emails will be a total nothing burger, and it may be that they didn't show because they weren't related to COVID origins. All that said, happy to hand them over in due course, along with other demands…

Cheers,

Peter

[1806] E-Mail from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Dr. Jeffrey Sturchio, Consultant, *et. al.* (Apr. 26, 2024, 5:42 PM).

5. Since February 2023, the Select Subcommittee has requested all communications between Dr. Daszak and the FBI. On April 11, 2024, Dr. Daszak transmitted a letter to the Select Subcommittee that stated, "[t]he Federal Bureau of Investigation were dealing with threats to EcoHealth Alliance, and to EcoHealth Alliance staff, including Dr. Daszak and his family. For this reason, and because some likely relate to active investigations, EcoHealth Alliance cannot provide these records to the SSCP. If you have further questions, please contact the Federal Bureau of Investigation."[1807] This is not true.

   In fact, a draft of Dr. Daszak's response letter more accurately stated, "[t]he Federal Bureau of Investigation were dealing with threats to EcoHealth Alliance and to Dr. Daszak and his family, ***as well as other intelligence matters***…"[1808]

   On April 19, 2024, Dr. Daszak in an email to his counsel, stated, "[m]ost emails are about threats…some are mixed in with responses to [the FBI] about covid origins and there are a few where I give them information on the situation in China, on people we've worked with etc. Its massively damaging to our reputation to reveal the discussions I had with them about this and we need to avoid this at all costs in my opinion."[1809]

> 1) #6, FBI email exchanges. Most emails are about threats and attacks and that is personal and sensitive. Some are mixed in with responses to them about covid origins and there are a few where I give them information on the situation in China, on people we've worked with etc. It's massively damaging to our reputation to reveal the discussions I had with them about this and we need to avoid this at all costs in my opinion. While it might be good for the American public to find out I was informing the IC about covid origins, the details in these emails are not for public consumption, will be used by the SSCP to politically attack us, and will completely undermine our ability as an organization to do work around the world – we'll be seen as spies, not scientists. I should not be punished for doing the right thing as an American citizen and helping the government when asked (as per the oath you swear when you become a citizen!).

6. On March 30, 2023, Dr. Daszak wrote that he transmitted documents to the Select Subcommittee that were "very reduced in scope" and that EcoHealth was not "sending every record" nor searching "all staff."[1810]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1807] Letter from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, *et. al*. (Apr. 11, 2024).
[1808] E-Mail from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Dr. Jeffrey Sturchio, Consultant, *et. al.* (Apr. 5, 2024, 1:06 AM) (emphasis added).
[1809] E-Mail from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Dr. Jeffrey Sturchio, Consultant, *et. al.(*Apr. 19, 2024, 9:05 PM).
[1810] E-Mail from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Dr. Jeffrey Sturchio, Consultant, *et. al*. (Mar. 20, 2023, 11:51 PM).

Message

From: Peter Daszak [redacted]
Sent: 3/20/2023 11:51:43 PM
To: [redacted]
CC: Alison Andre [redacted] Aleksei Chmura [redacted] Jeff Sturchio [redacted]
Subject: RE: [EXT] Urgent - need to check re. last weeks documents for the 2 House Committees

OK no problem. Once you send them let me know – I also want to see how quickly they respond.

We'll send you the next batch tomorrow (very reduced in scope), and aim for a third batch over to you on the 29th with some more detailed stuff.

I think that once they start looking through the first lot they might come back with questions, e.g. why we aren't sending every record, and why we aren't doing this for all staff. If we get that sort of pushback, we'll need to brainstorm next steps.

7. On February 14, 2023, Dr. Daszak, after receiving a letter from the Select Subcommittee, wrote an e-mail to his counsel, "[p]lease do what you can to slowly extend the timeline and significantly reduce the scope…"[1811]

Message

From: Peter Daszak [redacted]
Sent: 2/14/2023 12:26:26 AM
To: Jeff Sturchio [redacted]
Subject: FW: Letter from Chairmen Wenstrup, Comer, and Members of the SSCP to Dr. Daszak
Attachments: Response to SSCP letter to EHA 2.2.23.pdf

Importance: High

Just sent the email below and the letter (attached).

Please do what you can to slowly extend the timeline and significantly reduce the scope...

8. As a courtesy, the Select Subcommittee allows witnesses to review their transcribed interview transcripts prior to release. The Select Subcommittee is not required to accept any of the witnesses' edits. However, as a condition of this review, the witness agrees that "the transcript is property of the Committee and you and your client agree not to share or take pictures or digital representations of the transcript." Dr. Daszak violated this agreement and stated in an email that he took "screenshots of each of the issues that I think people will try to make news out of…"[1812]

[1811] E-Mail from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Dr. Jeffrey Sturchio, Consultant, *et. al.* (Feb. 14, 2023, 12:26 AM).
[1812] E-Mail from Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., to Dr. Jeffrey Sturchio, Consultant, et. al. (Jan. 25, 2024, 7:14 PM).

From: Peter Daszak [redacted]
Sent: Thursday, January 25, 2024 7:14 PM
To: [redacted] Alison Andre [redacted]
Cc: Aleksei Chmura [redacted] [redacted] 'Jeff Sturchio' [redacted]
Subject: RE: [EXT] EcoHealth Alliance - Interview Scheduling
Importance: High

Finished just now. Attached are the corrections.

It was a joyful read – a bit like a Colombo detective novel – where the committee are Colombo, and I'm the witless criminal...

Jeff – I'm going to send Aleksei all the screenshots of each of the issues that I think people will try to make news out of, and a note of what they represent. You can see the page numbers in the screenshots – not directly on the page, but on the DocSend frame. You might have to magnify each image, which is annoying, but at least you will see them

Again, these actions raise serious questions regarding Dr. Daszak's integrity and continue to support that he is not a good steward of taxpayer dollars.

FINDING: EcoHealth Alliance, Inc. Doctored Documents It Released to the Public.

On April 7, 2024, the Select Subcommittee received a tip regarding Dr. Daszak, Dr. Morens, and Dr. Keusch communicating regarding EcoHealth's research activities, including over Dr. Morens' Gmail.[1813] The tip included the following e-mail headers:

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1813] E-Mail from [REDACTED] to Select Subcomm. Staff (Apr. 7, 2024, 7:07 PM).

From: "David Morens" [redacted]
Sent: 7/13/2020 9:21:23 PM +0000
To: "Keusch, Gerald T" [redacted]
CC: Peter Daszak [redacted]
Subject: Re: PRO/AH/EDR> COVID-19 update (312): China, SARS-CoV2 origin, animal reservoir, WHO mission

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From: "David Morens" [redacted]
Sent: 4/26/2020 9:29:26 PM +0000
To: "Keusch, Gerald T" [redacted]
CC: Peter Daszak [redacted]; Aleksei Chmura [redacted]
Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

From: David Morens [redacted]
Sent: Sunday, April 26, 2020 11:47 AM
To: Peter Daszak [redacted]; keusch [redacted]
Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

From: "David Morens" [redacted]
Sent: 2/20/2022 10:08:29 PM +0000
To: Peter Daszak [redacted]
CC: Gerald Keusch [redacted]
Subject: Re: FW - emails from Erik Stemmy to say he's unable to talk with me anymore about our suspended R01

In response, the Select Subcommittee sent a document request to Boston University for responsive records from Dr. Keusch.[1814] After Dr. Keusch received the letter, he wrote, "[o]n the advice of the lawyers, however, I have stopped deleting anything that could be construed to be on the subcommittee's request list…" and "[m]y plan – but not necessarily one that the lawyers will concur is reasonable – is to tell the subcommittee that my views are well known…[and] that I have the right to have private conversations."[1815] Despite Dr. Keusch's plan, Boston University produced responsive documents to the Select Subcommittee.

On April 12, 2024, in response to the Select Subcommittee's letter, EcoHealth issued a press release stating the reporting "[did] not show the full text of the emails in question" and

[1814] Letter from Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability, to Dr. Gerald Keusch (Apr. 11, 2024).
[1815] E-Mail from Dr. Gerald Keusch to Dr. Peter Daszak, Pres., EcoHealth Alliance, Inc., et. al. (Apr. 20, 2024, 9:57 AM).

claimed to release "the full text of these email chains."[1816] In reality, Dr. Daszak personally doctored some of the documents and did not release the entirety of the full chains to the public.

Message

From: kuuipo9 [redacted]
Sent: 4/12/2024 12:56:29 AM
To: Peter Daszak [redacted] Jeff Sturchio [redacted] Keusch, Gerald T [redacted] feigelson [redacted]
CC: Aleksei Chmura [redacted]
Subject: Re: We'll release these selected emails tomorrow morning (Friday)

TY. d

Sent from Proton Mail Android

-------- Original Message --------
On 4/11/24 20:21, Peter Daszak wrote:

All – Apologies, I didn't realize how late it is. We'll plan on releasing these selective emails, with appropriate redactions tomorrow morning.

Jerry, David – they will not include any emails that would be embarrassing to either of you, but rather emails that show the normal process of a grantee trying to make sense of political interference in the NIH grant-making process...

Cheers,

Peter

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1816] *EcoHealth Alliance Releases Emails that are the Subject of False Allegations in the Press*, ECOHEALTH ALLIANCE, INC., (Apr. 12, 2024).

From: Peter Daszak <[redacted]
Sent: Thursday, April 11, 2024 8:00 PM
To: 'Jeffrey Sturchio' <[redacted]; 'David Morens' <[redacted]; 'Keusch, Gerald' [redacted] 'John Feigelson' <[redacted]
Cc: Aleksei Chmura <[redacted]

Subject: 3rd email chain to release tonight
Importance: High

Aleksei –plerase release this thread.

This is the final one – just 3 email chains – all 4 emails from the committee are included.

Jerry, David – I've not included some of your responses or earlier emails because there's no need at this point. This will help dampen down the stories.

We also now have HSGAC asking for these emails, so we can send them the urls to our statement once it's up online and that should be the end of it.

Cheers,

Peter

Message

From: Peter Daszak [redacted]
Sent: 4/11/2024 11:57:18 PM
To: Jeffrey Sturchio [redacted] David Morens [redacted] Keusch, Gerald [redacted]
Aleksei Chmura [redacted] John Feigelson [redacted]
Subject: 2nd chain to release tonight

Please do the same for the section between the XXXXX highlights below (it's only a bit of the chain).

Don't forget to REDACT David's gmail address, Jerry's email address, the sections in green block, and other stuff you think appropriate

Keep the highlighted sections in the released emails

Cheers,

Peter

These actions raise serious questions regarding Dr. Daszak's integrity and continue to support that he is not a good steward of taxpayer dollars.

FINDING:	Dr. Peter Daszak Provided False Statements to Congress in Violation of 18 U.S.C. 1001 and 18 U.S.C. 1621.

In comparing Dr. Daszak's testimony—both during his transcribed interview and public hearing—to available documents, it is likely Dr. Daszak provided false statements to the Select Subcommittee in violation of 18 U.S.C. 1001 and 18 U.S.C. 1621.

III. Dr. David Morens Likely Destroyed Evidence, Used Personal Email to Hide from Accountability, and Acted Unbecoming of a Federal Employee

In times of great peril and uncertainty, it is up to our nation's leaders to help guide the country and inspire confidence in the face of doubt. During the COVID-19 pandemic, there was no one that was looked to more than public health officials.

However, over the course of this investigation, the Select Subcommittee discovered documents and took testimony that raised serious concerns regarding wrongdoing on behalf of America's public health leaders.

FINDING:	Dr. David Morens Used Personal E-Mail Accounts to Avoid the Freedom of Information Act and Accountability.

FOIA was designed to ensure a public right of access to non-privileged federal records. It is the responsibility of federal employees to ensure official records are retained and maintained. Dr. Morens knowingly and intentionally used personal e-mails to avoid FOIA, transparency, and accountability.[1817] Dr. Morens displayed a pattern of disrespect and blatant disregard to his responsibility as a federal employee.

Dr. Morens took active steps to attempt to avoid accountability, going as far as informing other colleagues of his tactics. On July 13, 2020, Dr. Morens e-mailed Dr. Keusch and Dr. Daszak, articulating the exact steps he takes to "immunize" himself "from trouble."[1818]

From: David Morens [redacted]
Sent: 7/13/2020 5:21:23 PM
To: Keusch, Gerald T [redacted]
CC: Peter Daszak [redacted]
Subject: Re: PRO/AH/EDR> COVID-19 update (312): China, SARS-CoV2 origin, animal reservoir, WHO mission

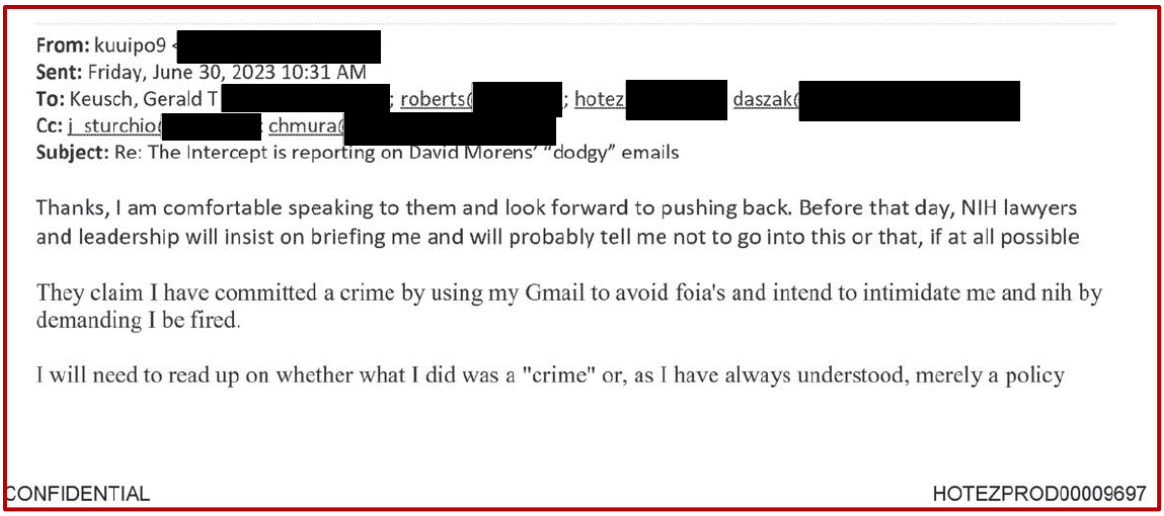
Yes, i am trying to catch these things, thanks. Some of these are intentional however, ss when the ajtmh paper comes out i will be publicly owning it, and safe to be foia'd. More important, i met with the head of our foia office and learned how to immunize myself from trouble Ergo, when i mess up don't worry, i think i am safe.

D

Sent from my iPhone
David M Morens
OD, NIAID, NIH

Dr. Morens goes as far as admitting he knew he was using Gmail to avoid FOIA. On June 30, 2023, from an end-to-end encryption e-mail account, Dr. Morens stated "I will need to read up on whether what I did was a 'crime' or, as I have always understood, merely a policy."[1819]

[1817] 5 U.S.C. § 552(b)(3) (2022).
[1818] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Gerald Keusch, M.D. (July 13, 2020, 5:21 PM).
[1819] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Gerald Keusch, M.D. (June 30, 2020, 10:31 AM).



From: kuuipo9 <[redacted]
Sent: Friday, June 30, 2023 10:31 AM
To: Keusch, Gerald T [redacted]; roberts([redacted]; hotez[redacted] daszak([redacted]
Cc: j_sturchio([redacted]; chmura([redacted]
Subject: Re: The Intercept is reporting on David Morens' "dodgy" emails

Thanks, I am comfortable speaking to them and look forward to pushing back. Before that day, NIH lawyers and leadership will insist on briefing me and will probably tell me not to go into this or that, if at all possible

They claim I have committed a crime by using my Gmail to avoid foia's and intend to intimidate me and nih by demanding I be fired.

I will need to read up on whether what I did was a "crime" or, as I have always understood, merely a policy

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This is unacceptable behavior. Even if he did not believe his actions to be a crime, Dr. Morens was still comfortable violating NIH policy. Not understanding an action is a crime is not an adequate defense for breaking the law and the trust of the American public.

Dr. Morens reminded colleagues around him of best practices for how to try to evade accountability. On August 1, 2022, Dr. Morens e-mailed several associates, reiterating the point that they needed to only use his personal Gmail, and to delete any other e-mail from their contacts.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

From: David Morens [redacted]
Sent: 8/1/2022 1:52:15 PM
To: Hotez, Peter Jay [redacted]
CC: Keusch, Gerald T [redacted] Peter Daszak [redacted] Morens, David (NIH/NIAID) [E] [redacted] Aleksei Chmura [redacted] Roberts, Rich [redacted] Jeff Sturchio [redacted]
Subject: Re: Upcoming hearing from a Senate Subcommittee on gain of function research

Guys, you are still sending to my NIH email. Please delete any email for me EXCEPT [redacted]@gmail.com

TY, d
David M. Morens, MD
[redacted]

IMPORTANT: My gmail frequently sends incoming messages to Trash, which is apparently not correctable. If you don't hear from me in a reasonable time, please try again, call, or use my NIH email address

IMPORTANT: For US Government-related email, please also reply to my NIAID address

This pattern of behavior appeared to escalate beyond utilizing a Gmail account to avoid FOIA. On April 4, 2023, Dr. Morens sent an e-mail to several colleagues from his end-to-end encrypted Proton account.[1820] This message was to alert them that the Select Subcommittee requested hard copies of Dr. Morens' Gmail account, and because he and his colleagues had inadvertently sent an e-mail to his Gmail account, their correspondence would be included. Dr. Morens then provided further instructions on how to proceed when communicating with him via e-mail. He stated, "[p]lease make sure [anything that you] send me 1) [goes] to my new account and 2) does not contain an e-mail trail with old emails containing my Gmail or [government] account."[1821]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1820] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Gerald Keusch, M.D. (Apr. 4, 2023, 7:02 AM).
[1821] *Id.*

From: kuuipo9 [redacted]
Sent: Tuesday, April 4, 2023 7:02 AM
To: Keusch, Gerald T [redacted] Peter Daszak [redacted] chmura@ [redacted]
j_sturchio@ [redacted]; hotez@ [redacted]; roberts [redacted]
Subject: Gmail foia

Peter and all,

Got a call from bldg 1 this morning at 630. The house committee wants hard copies of ALL my Gmail relating

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to YOU, Peter, Ian Lipkin, and any Bloomberg reporter I have ever communicated with. I have to provide this by COB today

I have spoken to and emailed with various Bloomberg reporters over the years but can't remember who I said what to. Most likely Jason Gale. Don't recall speaking with Ian lately. I think he and I had a Zoom call early in the pandemic. Please give him a heads up for me

Incidentally, in the past month or so you all have inadvertently sent emails to my Gmail account on a number of occasions

Please make sure u that anything you send me 1) goe.s to my new account and 2) does not contain an email trail with old emails containing my Gmail or govt account

Sorry for this inconvenience, just trying to protect us all. david

Sent from Proton Mail mobile

Dr. Morens knew using a separate personal e-mail account to evade FOIA was not allowed. Yet, he took, additional, further steps to try to avoid transparency and accountability. He created an additional, end-to-end encrypted e-mail address, and instructed his colleagues to send communications to that protected one, and to not "contaminant" the new e-mail by resending any old correspondences.

During the transcribed interview with Dr. Morens, the Select Subcommittee asked if he had any other e-mail accounts other than his work or personal ones.[1822] He answered no.

Dr. David Morens (January 18, 2024)

Q. Do have any other personal e-mail accounts like AOL of Yahoo? Gmail wasn't always around.

A. Did I have something before Gmail?

[1822] Transcribed Interview of David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases (Jan. 18, 2024) [hereinafter "Morens TI 2"].

Q. Before or contemporaneous to Gmail. When you say addresses, are you specifically talking about just the Gmail?

A. The only e-mail I had was my government e-mail and my Gmail.[1823]

Dr. Morens discussed avoiding FOIA and keeping communications on private e-mails to individuals outside of his circle of cohorts. On December 7, 2021, Dr. Morens e-mailed a member of the Board of EcoHealth Alliance Inc. Even though he was using his personal e-mail, he immediately recognizes himself as an NIH scientist, associates himself with Dr. Fauci, and clearly states he has to use a personal e-mail because his government address is susceptible to FOIA. Dr. Morens is clearly establishing he is using his G-mail to conduct business in his official capacity as an NIH employee, in an effort to evade FOIA.

On 12/7/21, 1:43 PM, "David Morens" [redacted] wrote:

Hi Nancye, you may not remember that we met a couple years ago, I can't exactly remember where, but I am writing you because I believe you are on the EcoHealth Board, and want to put in a word for Peter and the EcoHealth team, and all the great work they have been doing.

I am a scientist at NIH but because of death threats and general harassment of me and more particularly my boss, Tony Fauci, we have to keep all communications like this on private email so that it can't be

MORENS_SUBPOENA_019667

retrieved via a FOIA, as we have been FOIA's so many times we've all lost count, and we have had to set up a special FOIA team just over the issue of Peter and related matters.

Dr. Morens, via Dr. Keusch, expressed a concern, that apparently came from Dr. Fauci, that a FOIA could capture Dr. Morens' text messages on his government phone. Dr. Keusch stated that Dr. Morens is concerned about the privacy of text and other messages from his cell phone…This came from Tony in their conversation this morning."[1824]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1823] Morens TI 2, *supra* note 1822, at 51.
[1824] *Id.*

From: Keusch, Gerald T
To: Peter Daszak
Cc: Aleksei Chmura
Subject: RE: Draft response to Michael Lauer - please review
Date: Monday, October 25, 2021 4:25:31 PM

I just spent some time on the phone with David. He is concerned about the privacy of text and other messages from his cell phone to you and me because he has been using a government phone which permits personal conversations as well. So even things via gmail sent and received on his cell phone could be FOIA'able. This came from Tony in their conversation this morning.

David has multiple things going on this week, including medical appointments, closing on house, and the need to get himself a personal smart phone, and Tony has told him not to be in touch with you and EHA for the time being. He will stay connected to me and via me to you. He wanted to reiterate a couple of things. First, on the timeline to make it more specific with dates and details. Getting in touch with Stemmy is really important and being sure he is well informed, acknowledges the timeline and the communications you mention, and is on board because he will certainly be questioned. He also suggested that you discuss with him the need for NIH to check the records and to confirm when documents were filed and acknowledged. And that when you were aware that it was necessary to file the 5 year report the system shut you out and you presumed that was normal process as you were then into the new grant year 1.

Jerry

Dr. Morens continuously schemed to bypass FOIA. On November 18, 2021, Dr. Morens stated that he worked with NIH information technology staff to load "ant-hacking [sic] software on my phone and discussed the situation with me."[1825] Dr. Morens concluded that, because of these actions, his "gmail is now safe from FOIA."[1826]

[1825] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Gerald Keusch, M.D. (Nov. 18, 2021, 5:06 PM).
[1826] *Id.*

Date: Thu, 18 Nov 2021 5:06:31 PM -0500
Subject: Re: Opinion for WaPo
From: David Morens [redacted]
To: Keusch, Gerald T [redacted]

Jerry,

I am updating you on my computer and gag order situation.

With the help of our IT folks, I went over the whole computer and phone situation. They loaded some ant-hacking software on my phone and discussed the situation with me.

Basically, my gmail is now safe from FOIA and hacking on all of my devices, including government computer and phone, and my private computer and iPad.

Thus it should be safe to communicate safely with you, Peter, and others, as long as we use my private gmail.

You may have noticed that I have intentionally forwarded you news clips I get daily, sent from my govt email, but that is ok as long as you don't reply to that email. I have done this because this should not show up in a FOIA, is innocuous as it's just forwarding a third party item already in the public domain, and because it saves me forwarding to my own gmail and then on to you.

Please pass this on to Peter and I ask you both that NOTHING gets sent to me except to my gmail, and make sure that what gets sent to my gmail doesn't have a cc to another government employee who could be FOIA'd.

FOIA is a cornerstone piece of legislation that fosters transparency, accountability, and trust in government institutions and its leaders.[1827] It is essential to ensuring government entities are held accountable. This process allows for the scrutiny of records that otherwise might be overlooked, and has the potential to uncover corruption, inefficiency, or failures. FOIA informs the public and, as such, strengthens the foundations of democracy. It is meant to be a system that encourages transparency, not one to hide behind.

Dr. Morens testified that he understood his e-mails are considered a record pursuant to FOIA and that he was required to maintain these records.[1828] Further, Dr. Morens testified that he did not attempt to circumvent FOIA by using his personal e-mail accounts.

Dr. David Morens (January 18, 2024)

Q. …Are you aware of the Freedom of Information Act, which is commonly referred to as FOIA, and the obligations it places on federal agency employees?

[1827] 5 U.S.C. § 552 (2023).
[1828] Morens TI 1, *supra* note 1796, at 59-60.

A. I think I am, yes.

Q. And FOIA provides the public the right to request access to records from federal government agencies, correct?

A. Yes.

Q. And a federal agency employee's work e-mails are considered a record under FOIA, correct?

A. I think so, yes.

Q. And federal agency employees are required to maintain government records for FOIA requests to be properly processed, right?

A. Yes.

Q. FOIA is one of the main ways for the public to hold government accountable, and, as such, it is important that all federal agency employees maintain records properly for agency FOIA officers to be able to respond to FOIA requests fully and completely; is that correct?

A. Yes.

Q. Did you attempt to circumvent FOIA by using a personal e-mail account for official work discussions?

A. No.[1829]

FINDING: Dr. David Morens Deleted Federal Records in Violation of 18 U.S.C. 2071.

Maintaining and preserving federal records is the responsibility of all federal employees. In fact, it is a crime to delete or attempt to delete federal records. Accordingly, 18 U.S.C. 2071 states:

> Whoever willfully and unlawfully conceals, removes, mutilates, obliterates, or destroys, or attempts to do so, or, *with intent to do so* takes and carries away any record, proceeding, map, book, paper, document, or other thing, filed or deposited with any clerk or officer of any court of the United States, or in any public office, or with any judicial or public officer

[1829] *Id.*

> of the United States, shall be fined under this title or imprisoned not more than three years, or both.[1830]

This crime is a broad prohibition against destruction of government records or any attempts to destroy such records.[1831] Dr. Morens either intentionally deleted federal records or, if his records are automatically preserved, he intentionally attempted to delete federal records.

On January 21, 2022, Dr. Morens wrote, "[t]wice in the past, including a month or so ago, I deleted everything with [EcoHealth] people from my entire outlook…."[1832]

Message

From: David Morens [redacted]
Sent: 1/21/2022 10:34:21 PM
To: Peter Daszak [redacted]
CC: Jeff Sturchio [redacted] Keusch, Gerald T [redacted] Aleksei Chmura [redacted]
Subject: Re: FW: Article about our correspondence with NIH on the terminated-now-suspended grant

Twice in the past, including a month or so ago, I deleted everything with EHA people from my entire Outlook....

d
David M. Morens, MD
[redacted]

IMPORTANT: My gmail frequently sends incoming messages to Trash, which is apparently not correctable. If you don't hear from me in a reasonable time, please try again, call, or use my NIH email address

IMPORTANT: For US Government-related email, please also reply to my NIAID address

On August 1, 2022, Dr. Morens wrote, "hopefully no problems with the emails that came to me at my nih address. I deleted them quickly…"[1833]

[1830] 18 U.S.C. § 2071, *emphasis added*.
[1831] Criminal Resource Manual § 1663: Protection of Government Property—Protection of Public Records and Documents, U.S. Dep't of Justice.
[1832] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Peter Daszak, Ph.D., EcoHealth Alliance, Inc (Jan. 21, 2022, 10:34 PM).
[1833] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Peter Daszak, Ph.D., EcoHealth Alliance, Inc (Aug. 1, 2022, 1:39 PM).

From: David Morens [redacted]
Sent: 8/1/2022 1:39:02 PM
To: Peter Daszak [redacted]
CC: Hotez, Peter Jay [redacted] Keusch, Gerald T [redacted] Roberts, Rich [redacted] Jeff Sturchio [redacted] Aleksei Chmura [redacted]
Subject: Re: update...

This is all good news, thanks!

hopefully no problems with the emails that came to me at my nih address. I deleted them quickly and hopefully didn't reply to any (my phone doesn't show whether emails I get are to NIH or gmail, but when it's from you guys I assume it's to gmail).

d
David M. Morens, MD
[redacted]

IMPORTANT: My gmail frequently sends incoming messages to Trash, which is apparently not correctable. If you don't hear from me in a reasonable time, please try again, call, or use my NIH email address

IMPORTANT: For US Government-related email, please also reply to my NIAID address

On October 5, 2021, Dr. Morens discussed how he deleted a specific e-mail, one that contained langauge he did not want public.[1834]

From: David Morens [redacted]
Sent: Tuesday, October 5, 2021 6:28 PM
To: Peter Daszak [redacted]
Subject: Re: Talking with Elizabeth Warren's staff

Peter, i just got news that a foia picked up an email i sent you saying that tony commented he was braindead, jokingly of course. However, Ron Johnson is all over it and now after me. Tony will be pissed, rightly so. I deleted that email but i now learn that every email i ever got/sent since 1998 is captured and will be turned over, whether or not i instantly deleted it.

Gmail, phone, text.... i need to scrupulously rely on those exclusively. d

Sent from my iPhone
David M Morens
OD, NIAID, NIH

[1834] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Peter Daszak, Ph.D., EcoHealth Alliance, Inc (Oct. 5, 2021, 5:28 PM).

On February 24, 2021, Dr. Morens stated he deleted e-mails after forwarding them to his Gmail.[1835]

On Feb 24, 2021, at 9:21 AM, David Morens [redacted] wrote:

You are right, i need to be more careful. However, as i mentioned once before, i learned from our foia lady here how to make emails disappear after i am foia'd but before the search starts, so i think we are all safe. Plus i deleted most of those earlier emails after sending them to gmail. D

Sent from my iPhone
David M Morens
OD, NIAID, NIH

On Feb 23, 2021, at 21:53, Keusch, Gerald T [redacted] wrote:

We need you alive and well, so pay attention to the email address you use. If you get FOIA'ed and have to respond it will have Peter and, of lesser importance, me on the correspondence. The less we provide the enemy the better.

That said, thanks for planting the seed for this conversation to be. It will provide Tony with insights and it will be Peter who provides them - pointing out how amazingly connected (and important) he, Peter, is. Tony too.

Jerry

Gerald T. Keusch, M.D.
Professor of Medicine
Associate Director
National Emerging Infectious Diseases Laboratory
Boston University, Boston MA 02118

On September 10, 2021, Dr. Morens stated he deletes specific e-mails he doesn't "want to see in the New York Times."[1836]

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[1835] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Gerald Keusch, M.D. (Feb. 24, 2021, 9:21 AM).
[1836] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Jason Gale, Bloomberg, *et al.* (Sept. 10, 2021, 7:35 AM).

From: dmmorens[redacted] At: 09/10/21 07:35:15 UTC+10:00
To: [redacted]

Cc: Jason Gale (BLOOMBERG/ NEWSROOM:), rfgarry[redacted], kga1978[redacted]
edward.holmes@[redacted] angela.rasmussen[redacted] kessler@[redacted],
u6025689[redacted]

Subject: Re: here's the latest line of attack today...

Peter and colleagues,

As you know, I try to always communicate on gmail because my NIH email is FOIA'd constantly.

Yesterday my gmail was hacked, probably by these GoF assholes, and until IT can get it fixed I may have to occasionally email from my NIH account.

It spent a couple hours today but couldn't fix it.

Stuff sent to my gmail gets to my phone, but not my NIH computer.

Don't worry, just send to any of my addresses and I will delete anything I don't want to see in the New York Times.

d

David M. Morens, MD

[redacted]

IMPORTANT: My gmail frequently sends incoming messages to Trash, which is apparently not correctable. If you don't hear from me in a reasonable time, please try again, call, or use my NIH email address

IMPORTANT: For US Government-related email, please also reply to my NIAID address

On June 28, 2021, Dr. Morens stated, [t]hat email somehow feel into the hands of the Congressman, probably via FOIA of someone who didn't delete it, as I did (delete all of [Dr. Daszak's] emails and others relating to [COVID-19] origin…"[1837] Dr. Morens then proclaimed that "[t]he best way to avoid FOIA hassles is to delete all emails when you learn a subject is getting sensitive…"[1838]

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[1837] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (June 28, 2021, 4:10 PM).
[1838] *Id.*

On Jun 28, 2021, at 4:10 PM, Morens, David (NIH/NIAID) [E] [redacted]@gmail.com> wrote:

Sorry! On 18 April 2020, Peter Daszak emailed me and Tony, congratulating Tony on standing up for science. That email somehow fell into the hands of the Congressman, probably via a FOIA of someone who didn't delete it, as I did (delete all of Peter's emails and others relating to origin) when the shit

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started hitting the fan.

Anyway the Congressman got a copy of Peter D's email from someone at NIH, and he now wants to get any reply Tony and I or anyone else may have sent back to Peter. Mine was erased long ago (I verified that today) and I feel pretty sure Tony's was too. The best way to avoid FOIA hassles is to delete all emails when you learn a subject is getting sensitive... In any case, there is notthing here except opportunities to hassle, harrass, and huff and puff....

d

On June 16, 2022, Dr. Morens lamented the "old days" of conducting FOIAs, stating how they had to be done by hand.[1839] He stated that "[w]e are all smart enough to know to never have smoking guns, and if we did we wouldn't put them in emails and if we found them we'd delete them."[1840]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1839] E-Mail from David Morens, Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Peter Daszak, Ph.D., Pres., EcoHealth Alliance, Inc., *et al.* (June 16, 2020, 2:22 PM).
[1840] *Id.*

Date: Tue, 16 Jun 2020 2:22:55 PM -0400
Sent: Tue, 16 Jun 2020 2:22:54 PM -0400
Subject: Re: Two reporters might contact you in the next couple of weeks.
From: "Morens, David (NIH/NIAID) [E]" <[redacted]
To: Peter Daszak <[redacted]
CC: Gerald Keusch [redacted] Robert Kessler <[redacted] Aleksei Chmura [redacted]

The FOIAs are dreadful and paranoia-inducing. In the old days we had to do them ourselves, by hand. I mean finding and printing out thousands of emails coming in and going out. Now they sometimes FOIA text messages too. Many FOIAs turn up thousands of pages of docs, and of course, most of meaningless. We are all smart enough to know to never have smoking guns, and if we did we wouldn't put them in emails and if we found them we'd delete them. In my 22 years at NIAID I have never seen a FOIA that turned up useful information d

On January 18, 2024, in a transcribed interview, when asked if he'd ever deleted anything from his official account, Dr. Morens answered "[n]o."[1841]

Dr. David Morens (January 18, 2024)

Q. Did you ever delete anything from your official account or anything from your Gmail account that could be considered an official record?

A. No.[1842]

On May 22, 2024, during a public hearing, Dr. Morens was reminded of his answer and further asked if he deleted federal records. Dr. Morens answered, "[n]ot to my knowledge."[1843]

Dr. David Morens (May 22, 2024)

Q. Did you ever delete any official records?

A. Not to my knowledge, I mean, but again, at the issue of defining what is a Federal record, I deleted a lot of emails. I do it every day. But in my mind, they are trivial things not related to government business.[1844]

At his public hearing, Dr. Morens contended that he is unaware of what a federal record is. Dr. Morens also testified that at no point was a federal record defined as an "email."[1845] However, during Dr. Morens' transcribed interview he testified that he understood emails to be

[1841] Morens TI 2, *supra* note 1822, at 51.
[1842] *Id.*
[1843] *See generally*, Morens Hearing, *supra* note 387.
[1844] Morens Hearing, at 32, *supra* note 387.
[1845] Morens Hearing, at 7, *supra* note 387.

federal records.[1846] According to the HHS Policy for Records Management, "[a]ll records created or received by an official, employee, or contractor of HHS in the course of conducting federal government business for HHS are the property of HHS, wherever the record resides…"[1847] At the time Dr. Morens stated he was routinely deleting emails, he was a government employee for more than two decades. Federal employees are required to participate in records management training.

FINDING:	Dr. David Morens Shared Internal U.S. National Institute of Health Information with Dr. Peter Daszak and EcoHealth Alliance, Inc.

By virtue of his position within the Office of the Director of NIAID, Dr. Morens was privy to information the public was not. Through this access, Dr. Morens sent "one of his oldest and best friends," Dr. Daszak, numerous e-mails containing sensitive and, sometimes confidential, NIAID information surrounding EcoHealth Alliance's terminated grant or other materials relevant to the origins of COVID-19.[1848]

On March 31, 2021, Dr. Morens received an email from Ms. Hillary Hoffmann—an employee of NIAID's Office of Communications and Government Relations—notifying him that all requests for comment regarding the WHO's pandemic origins report should be directed to the National Security Council at the White House.[1849]

From: Hoffman, Hillary (NIH/NIAID) [E] [redacted]
Sent: Tuesday, March 30, 2021 1:32 PM
To: Morens, David (NIH/NIAID) [E] [redacted]
Cc: NIAID OCGR NSWB [redacted]
Subject: (FYI only): Origin of COVID-19 - Possible Interview

Hi Dr. Morens –

For your awareness (and in case she also reaches out to you directly), Mariana Lenharo followed up today on her request to speak with you or another NIAID expert about the WHO report, which as you know came out today.

MORENS_SUBPOENA_021231

We've been asked to refer requests for comment about the report to the National Security Council, and we will be directing her there.

Best,
Hillary

[1846] *See generally*, Morens Hearing, *supra* note 387.
[1847] HHS Policy for Records Management, U.S. DEPT. OF HEALTH & HUMAN SERVICES, *available at* https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-ocio-policy-for-records-management.html.
[1848] Morens TI 2, *supra* note 1822, at 26.
[1849] Morens Subpoena 021231

In an egregious display of Dr. Morens' willingness to share sensitive internal information, he forwarded this email chain directly to Dr. Daszak, Dr. Keusch, and Dr. Richard Roberts.[1850]

From: Morens, David (NIH/NIAID) [E] [redacted]@gmail.com>
Sent: Tuesday, March 30, 2021 4:25 PM
To: Roberts, Rich [redacted]>; Keusch, Jerry [redacted]; Peter Daszak <
[redacted]
Subject: Fwd: FW: (FYI only): Origin of COVID-19 - Possible Interview

Guys, see below..... The Biden admin apparently won't let any of us at NIH, including Tony, discuss the WHO report....

On the surface this sounds bad, but there is the possibility they just want one org to manage the message because they are trying to put out a fire. Or am I just Pollyanna? d

-------- Forwarded Message --------
Subject: FW: (FYI only): Origin of COVID-19 - Possible Interview
Date: Tue, 30 Mar 2021 17:43:09 +0000
From: Morens, David (NIH/NIAID) [E] [redacted]
To: David Morens [redacted]@gmail.com) [redacted]@gmail.com>

In an email dated September 7, 2021, Dr. Morens received an official email draft and deliberative responses to an Intercept reporter's inquiry regarding EcoHealth's NIAID grant. Sixteen minutes after receiving this email, Dr. Morens forwarded it to Dr. Daszak, Dr. Kessler, and Dr. Keusch, and commented that it illustrated that "behind the scenes, NIH [was] sticking up for EcoHealth."[1851]

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[1850] E-Mail from David Morens, M.D. to Gerald Keusch, M.D., *et. al.* (Mar. 30, 2021, 4:25 PM).
[1851] E-Mail from David Morens, M.D. to Peter Daszak, Ph.D., Pres., EcoHealth Alliance, Inc. (Sept. 7, 2021, 3:29 PM).

From: Morens, David (NIH/NIAID) [E] [redacted]@gmail.com >
Sent: Tuesday, September 7, 2021 3:29 PM
To: Peter Daszak [redacted]>; Robert Kessler [redacted]>; Keusch, Gerald T < [redacted] >
Subject: Fwd: FW: For urgent review: Question raised by EcoHealth Alliance Grant proposal

'Tis for crap like this that good Scotch whiskey is made, and tall glasses to pour it in..... Do Not Worry, behind the scenes NIH is sticking up for EcoHealth. d

MORENS_SUBPOENA_022208

------- Forwarded Message --------
Subject: FW: For urgent review: Question raised by EcoHealth Alliance Grant proposal
Date: Tue, 7 Sep 2021 19:27:20 +0000
From: Morens, David (NIH/NIAID) [E] [redacted]
To: David Morens [redacted]@gmail.com) [redacted]@gmail.com >

David

David M. Morens, M.D.
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520
[redacted](assistants: Kimberly Barasch; Whitney Robinson)
[redacted]

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From: Deatrick, Elizabeth (NIH/NIAID) [E] [redacted]
Sent: Tuesday, September 7, 2021 3:13 PM
To: Embry, Alan (NIH/NIAID) [E] [redacted] Haskins, Melinda (NIH/NIAID) [E] [redacted]
Selgrade, Sara (NIH/NIAID) [E] [redacted]
Cc: NIAID FOG [redacted] NIAID Media Inquiries [redacted] NIAID OCGR NSWB [redacted]
Subject: For urgent review: Question raised by EcoHealth Alliance Grant proposal

Good afternoon,
We received some follow-up questions from The Intercept regarding the GoF research documents they received (full inquiry below). DMID suggested the following language in order to respond to the reporter's questions. Her deadline is 5:00 PM today; would you be able to comment on these draft responses?

-

- Does this fit the NIH's definition of Gain of Function research?
    - The award to EcoHealth Alliance was reviewed by NIAID in the context of both the Gain-of-Function Research Funding Pause and the subsequent HHS P3CO Framework. In 2016, NIAID determined that the work was not subject to the Gain-of-Function (GoF) research pause because the proposed chimeras contained only S glycoproteins from distantly related bat coronaviruses, and also because contemporaneous data published at the time demonstrated that similar chimeric viruses exhibited reduced pathogenicity compared to wild type viruses. NIAID subsequently reviewed the work in the context of the P3CO Framework and determined it was not subject to P3CO because 1) P3CO requires a pathogen be highly transmissible and highly pathogenic in humans. Such chimeric work done in backbones of animal CoVs or mouse adapted CoVs (e.g. in WIV1 or SARS-CoVMA15) are performed in viral backbones unable to readily infect human cells; and 2) insertion of spike proteins from more distantly related animal CoVs would not be anticipated to increase pathogenicity or transmissibility in humans.
- Was anyone at NIH was aware of the work described above (and in the update presumably sent to you in late 2018 or early 2019)?
    - NIAID reviewed the work for compliance with both the GoF Research Funding Pause and the P3CO Framework as described above. Progress reports are reviewed and approved annually by NIAID staff.
- And if NIH was aware of the work, why was it allowed to continue?
    - This work was allowed to continue because it was not reasonably anticipated to increase pathogenicity or transmissibility either in mammals (Gain-of-Function Research Funding Pause) or in humans via the respiratory route (P3CO). These types of studies are important to understand whether newly discovered viruses have the potential to infect and cause disease in humans.
- She also wants to know: "was this process described above — the immediate stopping of working and notification of the NIAID Program Officer Grants Management Specialist, and appropriate institutional biosafety committee — set in motion on the case I wrote about earlier (ie the case of the novel coronaviruses replicating at 100s of times the rate compared to the original virus?"
    - It is not accurate to say that the chimeras replicated "at 100s of times the rate compared to the original virus." The figure you referenced clearly demonstrates that viral titers are equivalent by the end of the experimental time-course.

- Lastly, for awareness, she also sent one final follow-up which I have not had a chance to run past DMID yet: "And actually I found this similar statement, which was made in the 2017 NOA, which would pertain to the time period the research was being done: 'Per the letter dated July 7, 2016 to Mr. Aleksei Chmura at EcoHealth Alliance, should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes.' So my question is the same, but refers to the above warning: Were all experiments with these viruses stopped and did WIV provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcome?"

On August 11, 2021, Dr. Morens received an internal e-mail containing a draft response to a letter sent to Dr. Fauci by Senator Lindsey Graham (R-S.C.) and Senator Paul.[1852] Later that day, Dr. Morens forwarded this e-mail to Dr. Daszak, Dr. Keusch, and Dr. Kessler.[1853] In an apparent admission that this was an act of impropriety, Dr. Morens wrote "strictly CONFIDENTIAL, please. I fixed a few things in this but it seems like Tony is conveying the right message here."[1854]

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[1852] E-Mail from to David Morens, Senior Advisor to the Director, NIAID, to Peter Daszak, President, EcoHealth Alliance, Inc., *et al.* (Aug. 11, 2021, 12:52 PM).
[1853] *Id.*
[1854] *Id.*

From: Morens, David (NIH/NIAID) [E] [redacted]@gmail.com]
Sent: 8/11/2021 12:49:15 PM
To: dasz >> Peter Daszak [redacted] Keusch, Jerry [redacted] Robert Kessler [redacted]
Subject: Fwd: FW: For Review by 2 PM Tomorrow (8/12): Letter to Dr. Fauci from Sens Graham and Paul
Attachments: 2021-06-10 Graham Paul to Fauci.pdf; WSJ: The Science Suggests a Wuhan Lab Leak ; Draft Graham Paul WSJ Response_NIAIDreview.docx

Flag: Follow up

strictly CONFIDENTIAL, please. I fixed a few things in this but it seems like Tony is conveying the right message here.... d

-------- Forwarded Message --------
Subject:FW: For Review by 2 PM Tomorrow (8/12): Letter to Dr. Fauci from Sens Graham and Paul
Date: Wed, 11 Aug 2021 15:28:18 +0000
From: Morens, David (NIH/NIAID) [E] [redacted]
To: David Morens [redacted]@gmail.com) [redacted]@gmail.com>

David

David M. Morens, M.D.
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520
[redacted](assistant: Whitney Robinson)
[redacted]

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From: Hastings, Andrew (NIH/NIAID) [E] [redacted]
Sent: Wednesday, August 11, 2021 8:52 AM
To: Erbelding, Emily (NIH/NIAID) [E] [redacted] Hauguel, Teresa (NIH/NIAID) [E] [redacted] Stemmy, Erik (NIH/NIAID) [E] [redacted] Ford, Andrew (NIH/NIAID) [E] [redacted] Mulach, Barbara (NIH/NIAID) [E] [redacted] Fenton, Matthew (NIH/NIAID) [E] [redacted] Linde, Emily (NIH/NIAID) [E] [redacted] Morens, David (NIH/NIAID) [E] [redacted] NIAID DIR-OCGR [redacted] NIAID BUGS [redacted]
Cc: Harper, Jill (NIH/NIAID) [E] [redacted] Billet, Courtney (NIH/NIAID) [E] [redacted] Embry, Alan (NIH/NIAID) [E] [redacted] NIAID OCGR Leg [redacted]
Subject: For Review by 2 PM Tomorrow (8/12): Letter to Dr. Fauci from Sens Graham and Paul

Good morning,

Background:
Dr. Fauci received the attached Exec Sec letter on June 10th from Senators Lindsey Graham (R-SC) and Rand Paul (R-KY) regarding COVID-19 origins and, specifically, assertions raised in a *Wall Street Journal* commentary by Drs. Steven Quay and Richard Muller (the article is attached here for your reference). OCGR-Leg has used previously cleared documents to draft the attached response letter. We would appreciate your review and input.

Action:
By 2 PM Tomorrow, Thursday, August 12th, please review the attached draft response letter and provide any edits in tracked changes.

Please note that the audience for this letter are non-scientists and explanations of scientific concepts should be very high-level.

Let me know if you have any questions.

Thanks,
Drew

Cell #: [redacted]

Andrew K. Hastings, Ph.D.
Public Health Analyst
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
Bldg. 31, Room 7A17, MSC 2520
Bethesda, MD 20892-2520
[redacted]

On September 3, 2021, Mr. Folkers alerted NIH/NIAID staff to upcoming e-mail releases from requests from minority members of House Committee on Oversight and Reform.[1855] Mr. Folkers sent a follow up e-mail, alerting Dr. Morens and other staff that "900 pages of EcoHealth Alliance grant materials are going out (with redactions) today under a lawsuit with First Look Institute (The Intercept)."[1856] On September 5, 2021, Dr. Morens forwarded the e-mail from Mr. Folkers to Dr Daszak, Dr. Kessler, and Dr. Keusch.[1857]

[1855] E-Mail from Greg Folkers, Chief of Staff, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Nat'l Inst. of Allergy & Infectious Diseases Staff (Sept. 3, 2021, 9:29 AM).
[1856] E-Mail from Greg Folkers, Chief of Staff, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Nat'l Inst. of Allergy & Infectious Diseases Staff (Sept. 3, 2021, 12:09 PM).
[1857] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc., *et al.* (Sept. 5, 2021, 1:34 PM).

From: Morens, David (NIH/NIAID) [E] [redacted]@gmail.com>
Sent: Sunday, September 5, 2021 1:34 PM
To: Peter Daszak [redacted]; Robert Kessler [redacted]; Keusch, Jerry < [redacted]
Subject: Re: FW: ASF --- foia

But I think that's the important thing: since there is nothing to find, there is little they can do with it. Maybe at some point these nutters will move on to another conspiracy.... d

On 9/5/2021 1:19 PM, Peter Daszak wrote:

> Thanks for the heads-up. The 900 pages of grant material I think is the stuff we've been processing through with our lawyers. It includes the full proposal for our grant in China, reports etc. as well as our current U01. It's extremely upsetting that these will now be dragged through the mud, but the truth is, there's nothing unusual or embarrassing in there – everything is completely normal and above board, and both were highly scored by reviewers.

MORENS_SUBPOENA_022156

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In my view, this sort of stuff isn't going to get them the same level of interest that it did at the beginning of summer, so hopefully this will be another non-event, but let's see what drama they can dream up from it.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: +1-212-380-4474
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Morens, David (NIH/NIAID) [E] [redacted]@gmail.com>
Sent: Sunday, September 5, 2021 1:07 PM
To: Peter Daszak [redacted]; Robert Kessler [redacted]>; Keusch, Jerry [redacted]
Subject: Fwd: FW: ASF --- foia

Peter, have a stiffdrink before you read. But do not worry, this is thd new nomnal and there will be no "there" there..... d

-------- Forwarded Message --------
Subject: FW: ASF --- foia
Date: Sun, 5 Sep 2021 16:57:49 +0000
From: Morens, David (NIH/NIAID) [E] [redacted]
To: David Morens [redacted]@gmail.com) [redacted]@gmail.com >

David

David M. Morens, M.D.
CAPT, United States Public Health Service
Senior Advisor to the Director
Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A-03
31 Center Drive, MSC 2520
Bethesda, MD 20892-2520
[redacted](assistant: Whitney Robinson)

MORENS_SUBPOENA_022157

[redacted]

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From: Folkers, Greg (NIH/NIAID) [E] [redacted]
Sent: Friday, September 3, 2021 9:29 AM
To: NIAID OD AM [redacted]
Subject: RE: ASF --- foia

Further on FOIA

900 pages of EcoHealth Alliance grant materials are going out (with redactions) today under a lawsuit with First Look Institute (The Intercept). In OD.

ASF --- I do not think you need to look at this

Also, as folks may be aware, and apropos of my email late last night, Congress does not have to go through the FOIA. So the tranche from last night was not in the usual NIH FOIA channel.

From: Folkers, Greg (NIH/NIAID) [E]
Sent: Friday, September 3, 2021 12:09 AM
To: [redacted]
Subject: ASF --- foia

We have closely monitored foia document releases with an eye toward items that are new/different/potentially problematic in terms of people using them to cause mischief. Nothing recently has fallen into those categories

NOW --- What is new and will be released soon, perhaps tomorrow

Unredacted emails requested by minority members of House Committee on Oversight and Reform

In OD, please see

HOGR minority requested emails 9/2/2021 9:03 PM

ASF- I think it would be helpful for you to eyball **all** the redacted emails now being released in un-redacted form
For instance, for this entry, look at at the top one

NIH 2157 - 2161
NIH 2157 - 2161 redacted

We have gone through these, and the ones that might be worth a first look are:

FINDING: Dr. David Morens Violated His Oath of Office and Assisted Dr. Peter Daszak and EcoHealth Alliance, Inc Avoid Oversight.

In April 2020, NIH began enforcement actions into Dr. Daszak and EcoHealth. Dr. Morens was an employee of NIH at the time, and as such was bound by 5 U.S.C. 3331. This states:

> An individual, except the President, elected or appointed to an office of honor or profit in the civil service or uniformed services, shall take the following oath: "I, AB, do solemnly swear (or affirm) that I will support and defend the Constitution of the United States against all enemies, foreign and domestic; that I will bear true faith and allegiance to the same; that I take this obligation freely, without any mental reservation or purpose of evasion; and that I will well and faithfully discharge the duties of the office on which I am about to enter. So help me God." This section does not affect other oaths required by law.[1858]

Dr. Morens, as a civil servant, was required to faithfully discharge the duties of his office. Dr. Morens' failed to uphold this oath.

Among many examples, Dr. Morens' supporting Dr. Daszak's efforts to obstruct NIH's oversight of his grant is illustrative of Dr. Morens' failure to be a faithful steward of his office. These actions including advocating to EcoHealth's Board of Directors and editing letters Dr. Daszak was transmitting to NIH.

For example, on March 29, 2021, Dr. Morens edited a letter Dr. Daszak was sending to NIH.[1859] By editing this letter, Dr. Morens was actively undermining the position of the NIH and the U.S.

From: Morens, David (NIH/NIAID) [E] [redacted]
Sent: 3/29/2021 1:08:20 PM
To: Peter Daszak [redacted] Keusch, Jerry [redacted] Roberts, Rich [redacted]
CC: Aleksei Chmura [redacted]
Subject: Re: Response to Michael Lauer letters
Attachments: Response to NIH April 2021 re. reactivation and suspension of 2R01AI110964 dmm comments.docx

Peter, attached some edits for consideration. In general I think it makes the right points and presents a strong case. My comments are mostlly minor word-smithing, plus clarifying and simplifying as much as possible, since this will probably be read by Lauer but will perhaps be leaked and read by many others. david

[1858] 5 U.S.C. 3331.
[1859] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc., *et al.* (Mar. 29, 2021, 1:08 PM).

EcoHealth Alliance

Reinstatement and immediate suspension of 2R01AI110964
"Understanding the Risk of Bat Coronavirus Emergence"

Peter, add Lauer's title and address here...

PApril 2nd 2021

Formatted: Highlight

Dear Dr. Lauer,

This is a response to your letters of 7/8/2020 and 10/3/2020 regarding the reinstatement and immediate suspension of NIH grant 2R01AI110964, "Understanding the Risk of Bat Coronavirus Emergence", whichthat was previously terminated "for convenience" on 4/24/2020. In particular, I wish to respond to the conditions you state would need to be addressed in order for us to again haveprior to allowing access to the funds to continuedo this work.

As you know, immediately following NIH's request in the termination letter of 4/24/2020, we had ceased all contractual work with the Wuhan Institute of Virology. The terminationis lack of a funded relationship with the Iinstitute makes it extraordinarily difficult or even impossible to provide the information requested about a foreign organization -- as would be the case foror even a domestic one - that our organization neither works with currently nor has control overs.

Additionally, our collaborative work with the Wuhan Institute of Virology prior to 4/24/2020, and that planned as part of the currently suspended grant, is wholly unrelated to some of the NIH-stipulated conditions listed below, and pertains to events and situations that in no way involve EcoHealth Alliance. In short, feel, therefore, that most of the conditions below neitherdo not relate directly to EcoHealth Alliance's planned research as outlined in our renewal application, nor to the biosafety of our continued research funded by the suspended grant when the grant is reinstated in full.

However, despite our concerns about the relevance and fairness urrent difference in opinions regarding theseof conditions as set forth in detail below, I ha've made extensive efforts to satisfy the proposed additional conditions, and have laid the details out after each condition below. This includes volunteering to serveact as an expert on the WHO-China joint Mission on the Animal Origins of COVID-19, spending 1 month on the ground in China (including 2 weeks locked in quarantine), at great personal risk to me, to our organization, and to my family. I undertook this mission at a time when I have had increasing levels of personal attack and harassment, including death threats and a white-powder letter sent to my home address a few weeks after the details of our grant termination went public. This harassment continues to this day and is a direct result of dangerous conspiracy theories inadvertently amplified by NIH's grant termination.

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EHA_0005595

Below, I have detailed our response to each of the conditions placed on our suspended grant, in an effort to provide as much information as possible and to explain any limitations on what we can do to respond at this time. I look forward to your reply and feel certain we may discuss these points without legal counsel and as scientists focused on ourthe important and worthy research goals of the grant, which are focused on research to protect us all against further coronavirus spillover – something that is central to the goal of our R01 grant.

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
EcoHealth Alliance scientists were not part of the work that WIV conducted to determine the viral sequence of SARS-CoV-2. Given that WIV is a government entity, and that we have no logical business in seeking an aliquot of SARS-CoV-2 as part of the goals of our proposed collaboration, we believe this condition is effectively impossible for us to fulfil. In any caseAdditionally, the full genome of this viral sequence was uploaded to a freely-accessible database on January 6th 2020, and has been used widely by scientists in the USA (included those funded by NIH) and around the world in their work, undermining any reasonable request from a US non-profit to a Chinese Govt lab for an active sample of a pathogenic human virus.

Commented [MD([1]: Peter, this is nnot clear

2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
During the WHO mission to Chin, I asked about this directly to the staff at WIV, including the Director of the institute, the P4 Lab Director, Dr. Shi, and many others. The response given by wais that: "Some reports identified one formed laboratory worker as "missing". This person according the WIV staff was an alumnus who graduated in 2015 and is now working in a city in another province. They had been contacted and tested, and ascertained to be healthy. They are not willing to be interviewed for the WHO mission". This information has been summarized in the WHO-China Joint Study report, published 3/30/20.

3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
These cables were selectively leaked by a Washington Post reporter, who claimed that they indicate safety concerns, specifically that a scientist at the WIV spoke to a delegation from the US Embassy in Beijing and stated that the lab cannot function safely unless the number of laboratory technicians was increased. As part of EcoHealth Alliance's work in China over the past 15 years, including that funded by NIAID, I visited the US Embassy in Beijing regularly and was involved in discussions with these Embassy staff to set up a field visit to the WIV in order to generate goodwill between the US and China at a time when President Trump was planning a state visit. The trip described in these cables was a direct result of that. Prior to this newspaper article, I had been told by people privy to the cable's contents that the articles were positive and supportive of the work we were doing under NIAID funding, and that the trip was a success.

Commented [MD([2]: Peter, in this para you might say that the lab was built under international safety engineering standrads, adheres to international safety practice standards indicated in the BMBL, and the lead WIV staff were trained in safety in the United States by a known authority running the BSL-4 lab at the University of Texas Medical Branch in Galveston. You might also say that despite the claim of one individual, no safety concerns are known to have been alleged by others including safety experts

A few months later, the full text of these cables was released with minor redactions. It is clear from reading the full details that 1) the request for more laboratory technician support was simply a request

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for the funding ~~of~~ for more laboratory technician support, rather than a statement that the lab was unsafe; and 2) the cables were extremely positive about the importance of the collaborative work we were doing with WIV under NIAID funding. Thus, there was never any evidence of a safety concern at WIV. I have attached the cables to this email, and excerpted the relevant statements here:

"REDACTED noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from U~~G~~TMB are helping train technicians who work in the WIV BSL-4 lab. Despite this they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China."

"The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility~~v~~ is demonstrated by a recent publication on the origins of SARS. Over a five-year study REDACTED (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS Pathogens online on Nov. 30, 2017 (1), and ~~it~~ demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contains all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like corona viruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention."

4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.

The WIV staff categorically stated to the WHO mission that the lab is audited annually and no unusual events have been identified. The reports of diminished cell-phone traffic and roadblocks have not been verified or published by reliable sources. Diminished cell-phone traffic and roadblocks could be explained by a series of routine issues such as technical problems with the cell-phone facilities, visiting dignitaries, etc.

5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.

Since the last letter was received from NIH, WIV scientists have published an addendum to their original paper in *Nature* that described SARS-CoV-2 and compared it phylogenetically to RaTG13. In this

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Addendum, they explain the rationale for conducting work in this mine, and its connection to the miner's illnesses and deaths. Importantly, they explain that initial serological results did NOTnot show that these miners were positive for SARSr-CoVs as some media articles have suggested. Furthermore, they re-tested the miner samples using a range of assays, and found no evidence of SARS-related CoV, nor of SARS-CoV-2 antibodies or nucleic acid. During our meeting with WIV staff as part of the WHO mission I asked a series of questions about the miner's illnesses. Their response was that, while similar to COVID in that they had pneumonia, a common occupational hazard for miners, symptoms were also similar to other bacterial or fungal pneumonias. This, and the lack evidence of SARSr-CoV infection including absence of immune responses, led them to conclude that SARS or COVID infection had been ruled out aswas not the cause of these miner's illnesses.

6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
The WHO mission did exactly that, and while it was not a NIAID or U.S. National Academy of Sciences team, I am a member of the National Academy of Medicine and Chair of the US NASEM Forum on Microbial Threats. The 11 international expert members of the WHO team included leading authorities on epidemiology, animal-origin viral infections and One Health. Members of this team have extensive experience conducting lab audits (e.g. Peter Ben Embarek), running laboratories dealing with human clinical samples (e.g. Dominic Dwyer, Thea Fischer), and commissioning, managing and accrediting laboratories in foreign countries (myself, Fabian Leendertz). The WHO-China Joint Study report details the field site visits to multiple labs in Wuhan, including the WIV and summarizes our findings.

Additionally, after returning to the USA, and in the weeks prior to the publication of the report, I:

- Briefed Drs. Anthony Fauci and Clifford Lane of NIAID on the findings of the mission;
- Presented a full talk about the work to the NIAID COVID PI group that meets weekly
- Briefed FBI and other intelligence agency staff
- Briefed members of the US NASEM Forum on Microbial Threats
- Briefed staff on the White House National Security Council on the findings of this work
- Briefed staff on the House Committee for Science, Space, and Technology

7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System
This has been done, and all subawards fully reported as soon as we possibly could, once you notified us of this requirement in your letter of 7/8/2020.

8. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.

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All subrecipient agreements are attached. As we related~~told you~~ in response to your letter of 4/19/2020, which ~~that~~ asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of th~~is~~ award. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a well-known leading lab biosafety consultant based in southeast Asia who has extensive experience commissioning, accrediting and auditing BSL-2, & -3 labs, and has worked for over a decade at the BSL-4 Australian Animal Health Lab. We will be using their services for all foreign lab subcontractees to assess lab biosafety procedures and conduct audits. Finally, we have hired a Senior Field Veterinarian to oversee all EcoHealth Alliance fieldwork in the region and ensure compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, to pre-empt calls for further sanctions against our work given the continued daily attacks against EcoHealth Alliance in the press after the termination of our NIH grant.

Commented [MD([3]: Peter, should name these persons?

9. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
Over a 15 year period of collaboration with WIV, we have found no evidence to suggest that there was any element of noncompliance with any of the conditions of the grants we have worked together under. We deemed this laboratory to be extremely low risk, and continue to believe~~do~~ so.

10. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.
Given the intense geopolitical pressure around the accusations that WIV intentionally or accidentally released SARS-CoV-2 (something which the WHO mission deemed 'extremely unlikely'), requesting such information is not a plausible option at present.

Yours sincerely,

Dr. Peter Daszak

President

(t) +1 212-380-4462; (e) [HYPERLINK "mailto:daszak@ecohealthalliance.org"]

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FINDING: Dr. David Morens' Actions Violated U.S. National Institutes of Health Policy.

According to both Dr. Tabak and Dr. Fauci, Dr. Morens' actions violated NIH policy.

Dr. Lawrence Tabak (May 16, 2024)

Q. Shifting to some questions regarding NIH's document retention policies. Dr. David Morens, a senior advisor to Dr. Fauci for decades, wrote in an email to Dr. Daszak, "I learned from our FOIA lady here how to make emails disappear after FOIA but before the search starts, so I think we are all safe. Plus, I deleted most of those earlier emails after sending them to Gmail." Is that consistent with NIH document retention policies?

A. It is not.

Q. Does the NIH FOIA Office teach employees how to avoid transparency?

A. I certainly hope not.

Q. He also later wrote Dr. Daszak, "We are all smart enough to know to never have smoking guns, and if we did, we wouldn't put them in emails. And if we found them, we would delete them." Is that consistent with NIH document retention policies?

A. It is not.

Q. Finally, emails show that Dr. Morens would share internal discussions regarding upcoming FOIA releases with Dr. Daszak. He would then help Dr. Daszak craft responses to documents being released in these FOIAs. Are those actions consistent with NIH policies?

A. If those actions occurred, they would not be consistent.

Q. So, do these actions concern you, Dr. Tabak?

A. It does indeed.[1860]

Dr. Anthony Fauci (June 3, 2024)

Q. So, there's a troubling pattern of behavior from your inner circle, not just Dr. Morens but also your chief of staff, Mr. Folkers. Do you

[1860] Tabak Hearing, *supra* note 246.

agree that it violates NIAID policy to use personal email for official purposes?

A. The Dr. Morens issue that was discussed by this Committee violates NIH policy, yes.

Q. But does using official email—using a personal email for official business, does that violate policy?

A. Using a personal email for official business violates NIH policy.

Q. Does it violate NAID—NAI—NA—NIAID policy to delete records to intentionally avoid FOIA?

A. Yes.

Q. OK. On April 28, 2020, Dr. Morens edited an EcoHealth press release regarding the grant termination. Does that violate policy?

A. That was inappropriate, for him to be doing that for a grantee, as a conflict of interest, among other things.

Q. So, on March 29, 2021, Dr. Morens edited a letter that Dr. Daszak was sending to NIH. Does that violate policy?

A. Yes, it does.

Q. On October 25, 2021, Dr. Morens provided Dr. Daszak with advice regarding how to mislead NIH on EcoHealth's late progress report. Does that violate policy?

A. That was wrong and inappropriate and violated policy.

Q. On December 7, 2021, Dr. Morens wrote to the chair of EcoHealth's board of directors to, quote, ''put in a word,'' end quote, for Dr. Daszak. Does that violate policy?

A. He should not have done that. That was wrong.

Q. And that violates policy?

A. Well, I'm not sure of a specific policy, but I imagine it does violate policy. He should not have been doing that.[1861]

[1861] Fauci Hearing, *supra* note 231.

Dr. Lawrence Tabak (November 14, 2024)

Q. Thank you. Dr. Tabak, is Dr. David Morens still employed by the NIH?

A. He is still an employee.

Q. When you testified this summer, I asked you a series of questions about some of Dr. Morens' actions. The first was if the NIH FOIA Office teaches employees how to avoid FOIA. You said, and I quote, "I certainly hope not." Are you aware one of your former FOIA officers invoked the Fifth Amendment when asked about this issue?

A. I have learned that in the lay press, yes.

Q. I then asked if Dr. Morens' deleting emails and using his personal email to hide his relationship with EcoHealth was consistent with NIH policy, and you said no. Do you stand by that?

A. Absolutely.

Q. I then asked if Dr. Morens' sharing internal NIH deliberations or helping EcoHealth craft responses was consistent with NIH policy. You said, quote, "If those actions occurred, they would not be consistent." Do you stand by that?

A. Yes, sir, I do.

Q. If I show you proof of those actions, will you take more employment action against Dr. Morens?

A. Sir, we are taking the actions necessary in all cases –

Q. Okay. On the screen, in an email chain, it shows an internal NIH email about a draft letter from Dr. Fauci to Senators Graham and Paul. Dr. Morens forwarded this first to his Gmail and then to Dr. Daszak. Does sharing that draft letter violate NIH policy?

A. Yes, of course.

Q. The next email is the NIH informing Dr. Morens that the National Security Council will be leading the communications on the WHO origins report. Dr. Morens forwarded this first to his Gmail and then to Dr. Daszak. Does sharing this internal deliberation violate NIH policy?

A. Yes, it does.

Q. The next email is Dr. Daszak soliciting Dr. Morens' help in responding to NIH. Dr. Morens responded with his edits to the letter. But let's not take Dr. Morens' word for it. The attachment includes comments and track-changes done by Dr. Morens. Sir, does an NIH employee editing a grantee's oversight response to NIH violate NIH policy?

A. It absolutely is inappropriate.

Q. Have you read Dr. Morens' transcript of his interview before the Select Subcommittee?

A. I have not.

Q. Well, I'd like to share you with a few examples of his testimony. Dr. Morens was asked if he ever deleted an official record from his NIH account, and he answered, "No." On January 21st, 2022, Dr. Morens wrote, and I quote, "Twice in the past, including a month or so ago, I deleted everything with EHA people from my entire Outlook," end quote. Then, on August 1st, 2022, Dr. Morens wrote, and I quote, "Hopefully no problems with the emails that came to me at my NIH address. I deleted them quickly," end quote. Did Dr. Morens lie to Congress?

A. Sir, I don't know if he successfully deleted the emails or not. If he's a Capstone employee, he would not be able to delete the emails. It goes out of his –

Q. Well, he thought he deleted them.

A. Well, he may have that thought that, but if he's a Capstone employee –

Q. So –

A. -- it would remain in the record.

Q. -- it looks to me like he lied to Congress. And that's a felony.

A. Well, again, I –

Q. Dr. Morens was asked if he provided any advice to Dr. Daszak on how to respond to NIH oversight requests, and he said, "No." As we discussed and you saw earlier, Dr. Morens personally edited a letter

for Dr. Daszak that was directly related to NIH oversight of EcoHealth, the company at the center of the entire COVID pandemic. Did Dr. Morens lie to Congress?

A. Again, those types of actions would be completely inappropriate.

Q. "Yes." The answer is "yes." The evidence is on the screen. There's evidence that Dr. Morens violated numerous NIH policies and lied to Congress multiple times. Dr. Tabak, will you fire Dr. Morens?

A. As you know, we don't discuss specific personnel matters, but we are following all of our procedures to the letter.[1862]

Despite Dr. Morens violating NIH policy numerous times, he was not fired. Instead, NIH placed him on paid administrative leave for more than a year. As of November 14, 2021, nearly 18 months after the Select Subcommittee made Dr. Morens' actions public, he was still employed by NIH and Dr. Tabak refused to commit to fire him.[1863]

FINDING: Dr. David Morens Acted in a Manner Unbecoming of a Federal Public Health Official.

Working as a leader in the U.S. government should be a position that is held with honor and prestige. Being in a position of power, being able to affect change and help people in times of crisis, should be a responsibly accept with the utmost of respect. Yet, over the course of this investigation, the Select Subcommittee reviewed evidence of Dr. Morens blatantly abusing his position and making inappropriate, misogynistic, and crude statements. These statements express a lack of respect for the office he represents and the country he serves.

On November 18, 2021, Dr. Morens admitted that he tried to "pour cold water on [Dr. Walensky]" when Dr. Fauci was recommending her to be CDC Director, because she "wear[s] a skirt."[1864]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1862] Preparing for the Next Pandemic, *supra* note 230.
[1863] *Id.*
[1864] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Gerald Keusch, M.D. (Nov. 18, 2021).

You may be amused at the following aside that was a big surprise to me. He was asking my opinion about what is wrong with CDC and in the process said, out of the blue, that it was HE who got Rochelle Wolensky her job as CDC director by lobbying for her to Ron Klain.
Well, she does wear a skirt.... I poured a little cold water on her
but he was undeterred in thinking she is the cat's pajamas....

His main interest at the moment is making "universal" coronavirus vaccines, the COVID-19 end game, and things related to COVID immunity.
He's asked me to co-write with him 2 or 3 papers on these subjects, this being in the context of giving him ideas to communicate in his weekly WH press conferences and meeting with Biden's higher ups on a regular basis, plus being on TV.

Please give my best wishes to you-know-who david David M. Morens, MD [redacted]
[redacted]

[redacted]@gmail.com
[redacted](work)
[redacted](cell)

IMPORTANT: My gmail frequently sends incoming messages to Trash, which is apparently not correctable. If you don't hear from me in a reasonable time, please try again, call, or use my NIH email address

IMPORTANT: For US Government-related email, please also reply to my NIAID address

On May 22, 2024, during the Select Subcommittee's public hearing with Dr. Morens, Dr. Morens claimed that this was "a snarky joke" but admitted that it was indeed "misogynistic."[1865]

Dr. David Morens (May 22, 2024)

Q. Now, I have had differences, political and scientific differences, with Dr. Walensky. I have disagreed with her on infection acquired immunity. I have disagreed with her on school closures. I have disagreed with her on the lack of transparency of adverse outcomes from COVID-19 vaccines. I would have expected it when I was in medical school in 1982, and I can understand the embarrassment of having personal emails shared, but you were doing work-related stuff on your personal emails that you would have commented in an email. Dr. Fauci got Rochelle Walensky her job as CDC director by lobbying for her to Ron Klain. Well, she does wear a skirt. I poured a little cold water on her, but he was undeterred in thinking that she is the cat's pajama. So let me just say, am I the cat's pajama? Do you know how many women sit on this subcommittee? Do you know what it takes for any of these women to get elected to Congress, because I find your comments to be disgusting. You had an illustrious career, an amazing track to get to where you are. You are trusted with one of the highest positions in government to combat public health crisis, and instead of doing your job, you are too busy

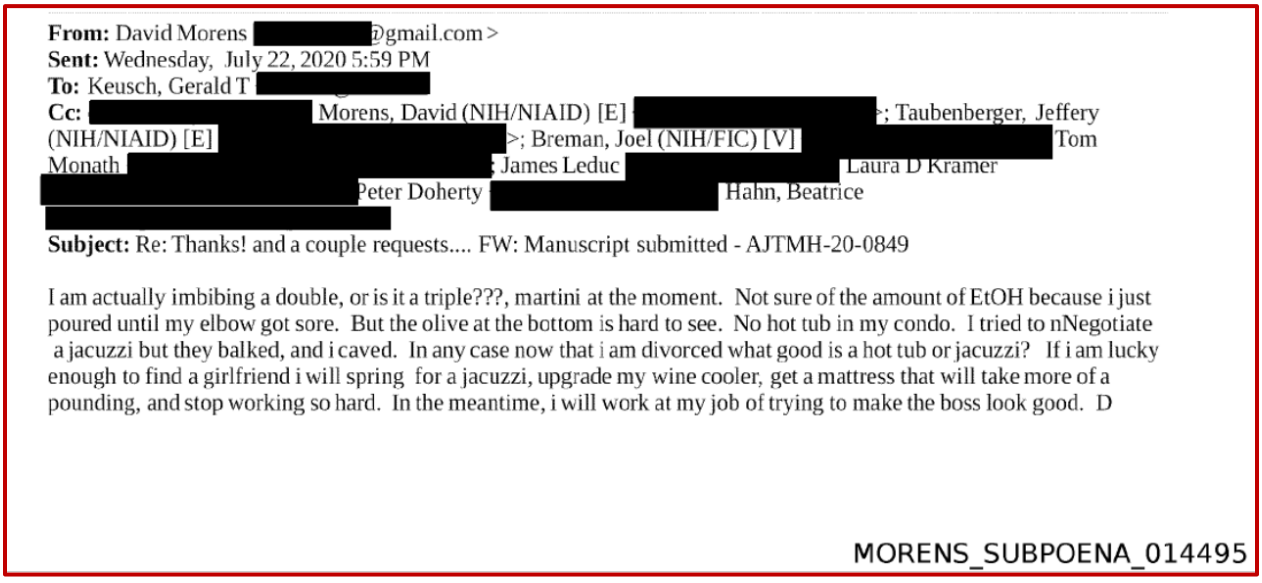
[1865] Morens Hearing, *supra* note 387, at 40-42.

worrying about avoiding FOIAs and challenging someone's position because they happened to wear a skirt. The American people deserve a whole lot better in their public servants. We don't need to worry about your trying to avoid FOIAs or what the quality of your mattress is, quite frankly, sir. You should be ashamed of your character and embarrassed. I am glad that you are, and you should in fact, apologize to this subcommittee, to Congress, and to our Nation. With that, I yield.

A. May I apologize to you and the Committee. It is a misogynistic statement, and, you know, it was the same snarky joking stuff, but let me say I have been an advocate –

Q. Sir, that is not a snarky joke. That is an underlying behavior that indicates how you approach women and how you think of women, and it is disgusting.[1866]

In this exchange, Congresswoman Mariannette Miller-Meeks (R-IA) also mentions the "quality of [Dr. Morens'] mattress."[1867] This is a reference to another remark made by Dr. Morens over email. The email was sent by Dr. Morens from his personal Gmail to a group of recipients which included NIH and NIAID colleagues. Specifically, Dr. Morens indicated that he planned to celebrate his submission of a manuscript by getting "a mattress that will take more of a pounding" so long as he was "lucky enough to find a girlfriend."[1868]



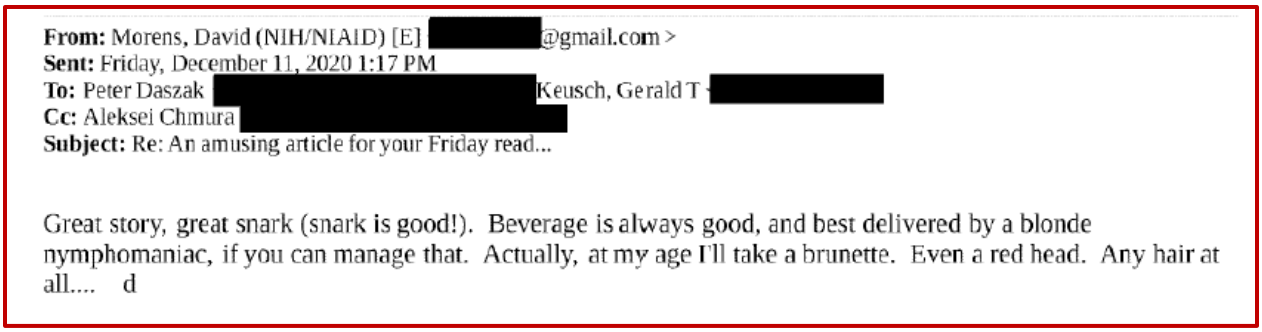
From: David Morens [redacted]@gmail.com>
Sent: Wednesday, July 22, 2020 5:59 PM
To: Keusch, Gerald T [redacted]
Cc: [redacted] Morens, David (NIH/NIAID) [E] [redacted]; Taubenberger, Jeffery (NIH/NIAID) [E] [redacted]; Breman, Joel (NIH/FIC) [V] [redacted] Tom Monath [redacted] James Leduc [redacted] Laura D Kramer [redacted] Peter Doherty [redacted] Hahn, Beatrice [redacted]
Subject: Re: Thanks! and a couple requests.... FW: Manuscript submitted - AJTMH-20-0849

I am actually imbibing a double, or is it a triple???, martini at the moment. Not sure of the amount of EtOH because i just poured until my elbow got sore. But the olive at the bottom is hard to see. No hot tub in my condo. I tried to nNegotiate a jacuzzi but they balked, and i caved. In any case now that i am divorced what good is a hot tub or jacuzzi? If i am lucky enough to find a girlfriend i will spring for a jacuzzi, upgrade my wine cooler, get a mattress that will take more of a pounding, and stop working so hard. In the meantime, i will work at my job of trying to make the boss look good. D

MORENS_SUBPOENA_014495

[1866] Morens Hearing, *supra* note 387, at 40-42.
[1867] *Id.*
[1868] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Gerald Keusch, M.D. (July 22, 2020, 5:59 PM).

In another email with the same theme, Dr. Morens made a misogynistic remark where he indicated that he preferred his beverages to be delivered to him by blonde "nymphomaniac"[s], but that he would settle for a brunette or red-haired woman, or one with "any hair at all" instead.[1869]



From: Morens, David (NIH/NIAID) [E] [redacted]@gmail.com >
Sent: Friday, December 11, 2020 1:17 PM
To: Peter Daszak [redacted] Keusch, Gerald T [redacted]
Cc: Aleksei Chmura [redacted]
Subject: Re: An amusing article for your Friday read...

Great story, great snark (snark is good!). Beverage is always good, and best delivered by a blonde nymphomaniac, if you can manage that. Actually, at my age I'll take a brunette. Even a red head. Any hair at all.... d

These misogynistic statements are bad enough, yet Dr. Morens also made other types of inappropriate statements. For example, on August 27, 2020, Dr. Morens implied that he should receive a "kickback" from Dr. Daszak after NIAID awarded EcoHealth a $7.5 million dollar grant which Dr. Morens said was "too much fooking money."[1870] Despite this statement, the Select Subcommittee did not find evidence that Dr. Morens in fact received a kickback. Regardless, it is wholly inappropriate for a federal employee of a grant making institution to suggest he is deserving of a kickback.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1869] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc., *et al.* (Dec. 11, 2020, 1:17 PM).
[1870] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc., *et al*. (Aug. 27, 2020, 7:54 PM).

From: Morens, David (NIH/NIAID) [E] [redacted]
Sent: Thursday, August 27, 2020 7:54 PM
To: Peter Daszak [redacted] Gerald Keusch [redacted]
Subject: Fwd: STAT: NIH awards $7.5 million grant to EcoHealth Alliance, months after uproar over political interference

Ahem.... do i get a kickback???? Too much fooking money! DO you deserve it all? Let's discuss.... Seriously, this is great news. Well deserved..., There is still justice in a Trump-infected universe.... d

Sent from my iPhone
David M Morens
OD, NIAID, NIH
Begin forwarded message:

From: "Folkers, Greg (NIH/NIAID) [E]" [redacted]
Date: August 27, 2020 at 18:04:15 EDT

MORENS_SUBPOENA_001152

To: NIAID COGCORE [redacted] NIAID OCGR Leg [redacted] NIAID OD AM [redacted]
Subject: STAT: NIH awards $7.5 million grant to EcoHealth Alliance, months after uproar over political interference

NIH awards $7.5 million grant to EcoHealth Alliance, months after uproar over political interference

By HELEN BRANSWELL @HelenBranswell AUGUST 27, 2020
Reprints

Dr. Morens dismissively characterized these statements as simply being "typical black humor" that he shared with Dr. Daszak and others.[1871]

Dr. David Morens (May 22, 2024)

Q. It does seem that you have a very cozy relationship with Peter Daszak. You indicated that he was a good friend. I mean, I have to after reading this email from Exhibit 6, on August 27, 2020, after NIH was awarded a $7.5 million grant to EcoHealth Alliance, you wrote to him and you asked, "Do I get a kickback? Too much fooking F-o-o-k-i-n-g money. Do you deserve it all? Let's discuss." Would you like to explain?

[1871] Morens Hearing, *supra* note 387 at 24.

A. That is typical black humor between people, like Peter and me and other folks who show up in these emails.

Dr. Morens also sent several emails that included violent or denigrating language about Senator Paul due to his oversight efforts regarding NIAID and investigation of the origins of COVID-19. Specifically, Dr. Morens wrote that Senator Paul "probably doesn't know how to "f*%$ himself."[1872]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1872] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc., *et al.* (July 25, 2021, 3:10 PM).

From: Morens, David (NIH/NIAID) [E] [redacted]@gmail.com>
Sent: Sunday, July 25, 2021 3:10 PM
To: Peter Daszak [redacted]; Keusch, Gerald T [redacted] Roberts, Rich [redacted]; Hotez, Peter Jay [redacted]
Cc: Robert Kessler [redacted]
Subject: Re: explicit language warning!

He probably doesn't know how to F*%$ himself, as he claerly failed anatomy. And all the other med school subjects. d

On 7/25/2021 3:20 PM, Peter Daszak wrote:

> Here's a story, not for the faint-hearted.
>
> It's a question for Senator (Dr.) Rand Paul, from a member of the public who called into one of his public Q&A sessions.
>
> Obviously, one doesn't condone this base level of

> public discourse, but I found myself curiously buoyed by it after his months of continued attacks…
>
> Here's a story:
>
> https://goodwordnews.com/senator- rand-paul-said-to-get-fucked-at-virtual-town-hall/
>
> Here's the video on Twitter:
>
> https://twitter.com/phil_lewis_/status/1418676246003818496?s=10

On June 10, 2020, Dr. Morens promised Dr. Daszak that they would "settle scores" and "kick some ass. Hard" regarding the COVID-19 origins debate and Dr. Daszak's terminated grant.[1873] Dr. Morens went so far as to say "[r]ectal spikes not prohibited."[1874]

From: Morens, David (NIH/NIAID) [E] [redacted]
Sent: 6/10/2020 8:56:43 PM
To: Peter Daszak [redacted]
Subject: Re: Guardian: Ignore the conspiracy theories: scientists know Covid-19 wasn't created in a lab

Number 2, we can try to change the world. Number 1, let's win this anti science battle, get you refunded and über funded, then settle scores and kick some ass. Hard. Rectal spikes not prohibited. D

Sent from my iPhone
David M Morens
OD, NIAID, NIH

Dr. Morens was Senior Scientific Advisor to Dr. Fauci for more than two decades. The unprofessional actions of Dr. Morens raise serious questions regarding the integrity of the Office of the Director of NIAID under Dr. Fauci's leadership.

On May 22, 2024, during Dr. Morens' hearing before the Select Subcommittee, Chairman Wenstrup stated:

> Frankly, some of the documents we received from Dr. Morens were difficult to read. I can't imagine saying some of the things, let alone putting them in writing. The select subcommittee uncovered communications in which Dr. Morens acted inappropriately and entirely unsuitably for a member of the public health service who receives a taxpayer-funded paycheck.[1875]

FINDING: Dr. David Morens Likely Provided False Testimony to Congress in Violation of 18 U.S.C. 1001.

The evidence presented throughout this report establishes Dr. Morens provided false testimony to the Select Subcommittee.

It is a federal crime to make materially false statements or representations to Select Subcommittee staff and Members of Congress during a Congressional investigation "conducted pursuant to the authority of any … subcommittee, … consistent with applicable rules of the House or Senate."[1876] In order to establish a violation of 18 U.S.C. 1001, the Department of Justice must prove the following elements of the crime beyond a reasonable doubt:

[1873] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc. (June 10, 2020, 8:56 PM).
[1874] *Id.*
[1875] Morens Hearing, *supra* note 387, at 5-6.
[1876] *See* 18 U.S.C. § 1001.

1) The defendant made the statement charged;
2) The statement was false, fictitious, or fraudulent;
3) The statement was material;
4) The defendant acted knowingly and willfully; and
5) The false statement pertained to a matter within the jurisdiction of the legislative branch of the government of the United States.[1877]

Dr. Morens was aware that it is a crime to make materially false statements during his transcribed interview. On January 18, 2024, prior to testifying at a transcribed interview before the Select Subcommittee, Select Subcommittee counsel warned Dr. Morens that, although he was participating in the transcribed interview voluntarily and was not sworn under oath, he was "required pursuant to Title 18, Section 1001 of the United States Code to answer questions from Congress truthfully." Select Subcommittee counsel informed Dr. Morens that this obligation to answer truthfully "also applie[d] to questions posed by congressional staff…" Dr. Morens was asked if he understood, and he responded in the affirmative. Additionally, Select Subcommittee counsel warned Dr. Morens that "[i]f at any time [he] knowingly ma[d]e false statements, [he] could be subject to criminal prosecution."[1878] Dr. Morens was asked if he understood, and he said yes.[1879] Finally, Select Subcommittee counsel asked Dr. Morens if there was "any reason [he was] unable to provide truthful testimony in today's interview."[1880] Dr. Morens said no.[1881]

Documents and information in possession of the Select Subcommittee likely establish that Dr. Morens violated 18 U.S.C. 1001.

During his transcribed interview, Select Subcommittee staff asked Dr. Morens if he ever purposefully used his personal e-mail account to avoid FOIA. He answered, "[n]o." Documents establish that to be a false statement.

Dr. David Morens (January 18, 2024)

Q. Did you ever circumvent FOIA by using a personal E-Mail account for official work discussions?

A. No.[1882]

During his transcribed interview, Select Subcommittee staff asked Dr. Morens if he ever deleted e-mails from his official account. He answered, "[n]o." Documents establish that to be a false statement.

[1877] *See United States v. Bowser*, 318 F. Supp. 3d 154, 171 (D.D.C. July 17, 2018) (setting forth the elements of the statute).
[1878] Morens TI 2, *supra* note 1822, at 15.
[1879] *Id*.
[1880] *Id.* at 16.
[1881] Morens TI 2, *supra* note 1822, at 60.
[1882] *Id.*

Dr. David Morens (January 18, 2024)

Q. Did you ever delete anything from your official account or anything from you G-Mail account that could be considered an official record?

A. No.[1883]

During his transcribed interview, Select Subcommittee staff asked Dr. Morens if ever assisted Dr. Daszak or EcoHealth in their responses to NIH oversight efforts. He answered, "[n]o." Documents establish that to be a false statement.

Dr. David Morens (January 18, 2024)

Q. Did you ever assist in any of the drafting of the correspondence that [Dr. Daszak] sent back [to NIH]?

A. No. No.[1884]

During his transcribed interview, Select Subcommittee staff asked Dr. Morens if he possessed or used any other personal e-mail accounts other than his Gmail. He answered, "[t]he only e-mail I had was my government e-mail and my Gmail." Documents establish that to be a false statement.

Dr. David Morens (January 18, 2024)

Q. Do have any other personal e-mail accounts like AOL of Yahoo? Gmail wasn't always around.

A. Did I have something before Gmail?

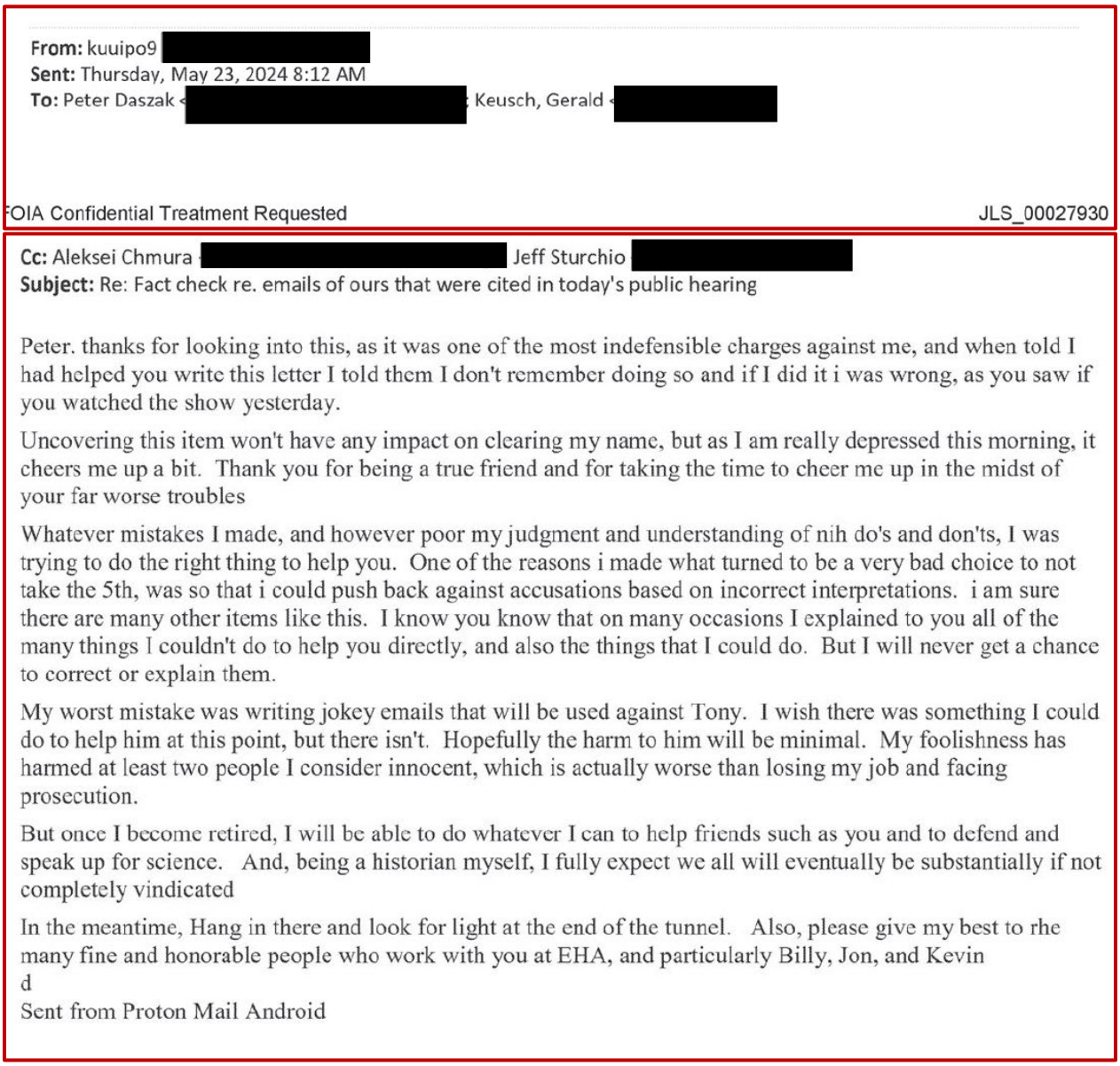
Q. Before or contemporaneous to Gmail. When you say addresses, are you specifically talking about just the Gmail?

A. The only e-mail I had was my government e-mail and my Gmail.[1885]

Prior to Dr. Morens May 22, 2024 public hearing, the Select Subcommittee was under the impression he planned to invoke his Fifth Amendment right against self-incrimination and refuse to testify. A couple hours before the hearing, Dr. Morens decided to proceed with testifying. On May 23, 2024, Dr. Morens lamented to Dr. Daszak, "[w]hatever mistakes I made, and however poor my judgment and understanding of nih do's and don'ts, I was trying to do the right thing to

[1883] Morens TI 2, *supra* note 1822, at 51.
[1884] Morens TI 2, *supra* note 1822, at 136.
[1885] Morens TI 2, *supra* note 1822, at 51.

help you. One of the reasons I made what turned to be a very bad choice not take [sic] the 5th…"[1886]



From: kuuipo9 [redacted]
Sent: Thursday, May 23, 2024 8:12 AM
To: Peter Daszak <[redacted]; Keusch, Gerald <[redacted]

FOIA Confidential Treatment Requested JLS_00027930

Cc: Aleksei Chmura <[redacted] Jeff Sturchio [redacted]
Subject: Re: Fact check re. emails of ours that were cited in today's public hearing

Peter. thanks for looking into this, as it was one of the most indefensible charges against me, and when told I had helped you write this letter I told them I don't remember doing so and if I did it i was wrong, as you saw if you watched the show yesterday.

Uncovering this item won't have any impact on clearing my name, but as I am really depressed this morning, it cheers me up a bit. Thank you for being a true friend and for taking the time to cheer me up in the midst of your far worse troubles

Whatever mistakes I made, and however poor my judgment and understanding of nih do's and don'ts, I was trying to do the right thing to help you. One of the reasons i made what turned to be a very bad choice to not take the 5th, was so that i could push back against accusations based on incorrect interpretations. i am sure there are many other items like this. I know you know that on many occasions I explained to you all of the many things I couldn't do to help you directly, and also the things that I could do. But I will never get a chance to correct or explain them.

My worst mistake was writing jokey emails that will be used against Tony. I wish there was something I could do to help him at this point, but there isn't. Hopefully the harm to him will be minimal. My foolishness has harmed at least two people I consider innocent, which is actually worse than losing my job and facing prosecution.

But once I become retired, I will be able to do whatever I can to help friends such as you and to defend and speak up for science. And, being a historian myself, I fully expect we all will eventually be substantially if not completely vindicated

In the meantime, Hang in there and look for light at the end of the tunnel. Also, please give my best to rhe many fine and honorable people who work with you at EHA, and particularly Billy, Jon, and Kevin
d
Sent from Proton Mail Android

[1886] E-Mail from David Morens, M.D., Senior Advisor, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, to Peter Daszak, Ph.D., EcoHealth Alliance, Inc., *et al.* (May 23, 2024, 8:12 AM).

IV. New York Governor Kathy Hochul's Administration Withheld Key Documents from the Select Subcommittee Based on Claimed Privilege

As previously discussed in this report, age and comorbidities were the most important risk factor for predicting hospitalization and death from COVID-19. This fact was known by then New York State Governor Andrew Cuomo in the earliest days of the pandemic. Despite knowing the threat COVID-19 posed to the elderly, the Cuomo Administration issued the March 25 Directive that ordered potentially COVID-19-positive nursing home residents be admitted or re-admitted to a nursing home and prohibited testing.[1887] The Cuomo Administration sought to cover-up the impact of the March 25 Directive by continually altering the methodology of how nursing home fatalities were counted and by repeatedly asserting the March 25 Directive followed federal guidance—from both the U.S. Centers for Medicare and Medicaid Services (CMS) and U.S. Centers for Disease Control and Prevention (CDC)—regarding protecting residents in nursing homes and other long-term care facilities.[1888]

During the 117th and 118th Congresses, the Select Subcommittee's predecessor sent numerous document request letters to the Cuomo Administration and even invited Mr. Cuomo to testify. All of these were ignored. According to documents obtained by the Select Subcommittee and the current posture of Mr. Cuomo and his allies, they believe this investigation to be illegitimate.[1889]

From: Richard Azzopardi

Sent: Friday, July 10, 2020 12:27 PM
To: Kyle Kotary; Jonah Bruno (health.ny.gov); Peter Ajemian; Dani Lever; Gareth Rhodes (dfs.ny.gov); Jim Malatras
Cc: Gary C Holmes (health.ny.gov); Jill E Montag (health.ny.gov)
Subject: Re: Jim please see answers below. Re: FLAG: ProPublica deep dive into DOH NH study, Sapien/Sexton

On yesterday's bullshit letter, this is whati gave.

> "These travel sized Trumps can write as many election-year partisan attacks on taxpayer-funded letterhead as they want, but the fact is are they have no authority to launch their own inquiry, under a 2017 opinion by the Trump Justice Department which states: 'Individual members of Congress, including ranking minority members, do not have the authority to conduct oversight in the absence of a specific delegation by a full house, committee, or subcommittee.' Additionally despite the federal lab not delivering a positive New York Covid-19 case until March 1 experts now say it was here in February if not earlier and the DOH study, which was peer reviewed by experts at Northwell Health and Mount Sinai, showed definitively that the spike in facility deaths was early, likely caused by asymptomatic staffers through no fault of their own and predated the March 25th directive. We're used to Republicans denying science but now they are screeching about time, space and dates on a calendar to distract from the federal government's many, many, embarrassing failures. No one is buying it, knock it off and wear a mask."
>
> https://www.justice.gov/olc/file/966326/download

[1887] March 25 Directive, *supra* note 894.
[1888] Cuomo TI, *supra* note 907, *at* 129; Zucker TI, *supra* note 905, at 90-91.
[1889] E-Mail from Richard Azzopardi, to Kyle Kotary, *et al.,* (July 10, 2020, 12:27 PM).

Mr. Cuomo's successor, current New York State Governor Kathy Hochul, promised to be "fully transparent" regarding COVID-19 in nursing homes.[1890] Once the Select Subcommittee began its investigation in 2023, it became evident that the Hochul Administration was not fully transparent regarding the former-Cuomo Administration's failures.

In May 2023, the Select Subcommittee requested documents and information from New York and two other states that had orders similar to New York's March 25 Directive.[1891] On October 10, 2023, the Select Subcommittee sent a follow-up request to the Executive Chamber.[1892] On November 6, 2024, the Select Subcommittee sent a third letter to the Executive Chamber.[1893] Eight months after the original request, in February 2024, the Executive Chamber produced its first tranche of documents.

FINDING:	The Executive Chamber's Production Is Incomplete, Overly Redacted, and Withheld Thousands of Responsive Records Without Apparent Legal Basis.

While, as of November 29, 2024, the Executive Chamber has produced nearly 375,000 documents, it is apparent that it has failed to fully fulfill the Select Subcommittee's requests. As outlined below, the documents produced by the Executive Chamber are incomplete and substantially redacted—often, without apparent legal basis. Further, there are responsive documents the Select Subcommittee knows exist—through public reporting and witness testimony—that were not included in the productions.

Additionally, the Executive Chamber withheld thousands of pages of responsive documents pursuant to tenuous legal privileges. At the beginning of this investigation, it was not apparent that the Executive Chamber would provide the Select Subcommittee with a privilege log to explain redactions until the Select Subcommittee requested one. Finally, the Executive Chamber did not inform the Select Subcommittee it was withholding responsive documents until all the productions had been completed and the privilege log was produced.

This resulted in the House Committee on Oversight and Accountability issuing a subpoena to Governor Hochul on September 10, 2024.[1894]

[1890] Matt Sedensky, *Cuomo Exit Isn't Stopping Push For Answers on Nursing Homes*, NBC NEW YORK (Aug. 13, 2021).
[1891] Letter from Brad Wenstrup, D.P.M., Chairman, H. Select Subcomm. on the Coronavirus Pandemic & Nicole Malliotakis, Member of Congress, to Kathy Hochul, Governor of New York (May 19, 2023); Letter from Brad Wenstrup, D.P.M., Chairman, H. Select Subcomm. on the Coronavirus Pandemic, to Phil Murphy, Governor of New Jersey (May 19, 2023); Letter from Brad Wenstrup, D.P.M., Chairman, H. Select Subcomm. on the Coronavirus Pandemic & John Joyce, M.D., Member of Congress, to Josh Shapiro, Governor of Pennsylvania (May 19, 2023).
[1892] Letter from Brad Wenstrup, D.P.M., Chairman, H. Select Subcomm. on the Coronavirus Pandemic & Nicole Malliotakis, Member of Congress, to Kathy Hochul, Governor of New York (Oct. 10, 2023); Counsel to the New York State Department of Health stated that it had delivered a responsive set of documents to the Select Subcommittee on June 2, 2023 via FedEx. The Select Subcommittee never received this production.
[1893] Letter from Brad Wenstrup, D.P.M., Chairman, H. Select Subcomm. on the Coronavirus Pandemic & Nicole Malliotakis, Member of Congress, to Kathy Hochul, Governor of New York (Nov. 6, 2023).
[1894] Letter from Brad Wenstrup, D.P.M., Chairman, H. Select Subcomm. on the Coronavirus Pandemic, to Hon. Kathy Hochul, Governor of New York (Sep. 10, 2024).

The Executive Chamber Failed to Adequately Notify the Select Subcommittee it was Withholding Responsive Documents

Prior to production of documents, the Executive Chamber did not inform the Select Subcommittee it would be withholding responsive documents or redacting certain information. Once the Executive Chamber began producing documents, the cover letter accompanying the first production of documents from the Executive Chamber stated that the Executive Chamber was producing "non-privileged" documents, but did not explicitly state that responsive documents were being withheld or produced with redactions.[1895]

On February 14, 2024, considering the redacted documents, the Select Subcommittee requested a privilege log for all redactions.[1896] Counsel for Executive Chamber responded that they would be producing a privilege log after the production of all non-privileged documents.[1897] At that point, the Executive Chamber did not explicitly inform the Select Subcommittee that, in addition to redacting documents, it was actively withholding responsive documents.

On September 24, 2024, after being served with the subpoena, Counsel for the Executive Chamber transmitted a letter to the Select Subcommittee.[1898] Among other things, this letter is misleading regarding the production of the privilege log. As explained above, the Select Subcommittee requested a privilege log. The Executive Chamber's letter conspicuously leaves this request out and simply states that it "notified the Majority Staff in writing that we would be preparing and producing a privilege log for review once we finish our review and production of non-privileged documents."[1899]

Further, the September 24 Letter states the Executive Chamber has been "clear and consistent about our approach towards privileged documents from the very outset of our review."[1900] The September 24 Letter claimed "our production of various redacted documents further emphasized that certain documents were being withheld on the basis of privilege."[1901] The Executive Chamber's apparent position was that because some documents were partially redacted, the Select Subcommittee is to assume that thousands of other documents were being withheld in their entirety.

The Executive Chamber Withheld Thousands of Pages of Responsive Documents Pursuant to Tenuous Legal Privileges

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[1895] Letter from Stephen M. Juris, Counsel, New York Executive Chamber, to Mitchell Benzine, Staff Dir., Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability (Jan. 16, 2024).
[1896] E-mail from Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability Staff to Stephen M. Juris, Counsel, New York Executive Chamber (Feb. 14, 2024, 2:34 PM).
[1897] E-mail from Stephen M. Juris, Counsel, New York Executive Chamber to Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability Staff (Apr. 24, 2024, 4:21 PM).
[1898] Letter from Stephen M. Juris, Counsel, New York Executive Chamber, to Mitchell Benzine, Staff Dir., Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability (Sept. 24, 2024).
[1899] *Id.*
[1900] *Id.*
[1901] *Id.*

With regard to the privilege log, it provided insufficient, and in some areas incomplete, information for the Select Subcommittee to adequately identify and assess the documents or information that the Executive Chamber redacted or withheld. In particular, the privilege log includes email entries that entirely redact the subject of the email.[1902]

Moreover, the communication descriptions within the privilege log are entirely too vague to adequately inform the Select Subcommittee of the documents at issue. For example, the description is limited in numerous entries to an "[e]mail thread reflecting governmental deliberations regarding NYS information."[1903]

The Executive Chamber claimed that the deliberative process privilege—assuming it is recognized—applies to communications from individuals apparently not employed by New York state government. Among other things, the Executive Chamber withheld documents and communications related to the July 6, 2020 NYSDOH report, titled, "Factors Associated with Nursing Home Infections and Fatalities in New York During the COVID-19 Global Health Crisis [hereinafter, "NYDOH Report"]—which was explicitly requested by the Select Subcommittee's November 6 Letter—that were sent by Michael Dowling of Northwell Health,[1904] David Grabowski of Harvard University,[1905] and individuals from McKinsey & Company.[1906]

Although the Select Subcommittee does not recognize the deliberative process privilege, even if it did, the Executive Chamber's assertions are incorrect and overly broad. The deliberative process privilege serves to protect government personnel's internal, predecisional communications—not external communications with non-governmental personnel that are purely factual in nature or that are not deliberative in nature.[1907] The Executive Chamber has not explained why communications from, to, or among individuals who were not employed by the Executive Chamber, and in many instances, were not even employed by the State of New York, are protected by the deliberative process privilege, even if it were to be recognized here. Nor has the Executive Chamber explained why any potential privilege claim was not waived by the inclusion of these third parties.

[1902] *See* NYSEC_SUBCOMM_00374006; NYSEC_SUBCOMM_00374007; NYSEC_SUBCOMM_00374047; NYSEC_SUBCOMM_00374053.

[1903] NYSEC_SUBCOMM_00374006-07; NYSEC_SUBCOMM_00374007; NYSEC_SUBCOMM_00374030; NYSEC_SUBCOMM_00374032; NYSEC_SUBCOMM_00374042-43; NYSEC_SUBCOMM_00374046-47. NYSEC_SUBCOMM_00374052-53.

[1904] NYSEC_SUBCOMM_00374009 (Email from Michael Dowling, Northwell Health, to Melissa DeRosa, Secretary to the Governor, New York State (June 30, 2020)).

[1905] NYSEC_SUBCOMM_00374009 (Email from David Grabowski, Professor, Harvard, to Melissa DeRosa, Secretary to the Governor, New York State (July 5, 2020)).

[1906] NYSEC_SUBCOMM_00374030; NYSEC_SUBCOMM_00374037; NYSEC_SUBCOMM_00374039-40.

[1907] The deliberative process privilege serves to "protect the deliberative process of the government by ensuring that person[s] in an advisory role would be able to express their opinions freely to agency decision makers." *Matter of Moody's Corp. & Subsidiaries v New York State Dept. of Taxation & Fin.*, 35 N.Y.S.3d 785, 790 (N.Y. App. Div. 2016) (internal quotation marks, brackets and citations omitted). It applies to records that are "deliberative," meaning "communications exchanged for discussion purposes not constituting final policy decisions." *Id*. at 1001 (internal quotation marks and citations omitted).

If recognized, the deliberative process privilege may apply to records prepared by consultants retained by the government.[1908] However, the Executive Chamber has failed to provide a reasonable explanation for claims of deliberative process privilege for communications involving third parties. Namely, whether the third-party individuals were retained as a consultant and the communication withheld involved a record produced in furtherance of their retention.

The Executive Chamber also unduly extended the attorney-client privilege in order to withhold responsive documents and communications. For instance, the Executive Chamber claimed that the privilege applied to communications from non-attorneys, including but not limited to communications from Senior Executive Chamber staff. In one example, the Executive Chamber withheld four consecutive emails from an administrative assistant on the apparent grounds that they were covered by attorney-client privilege.[1909] While the Executive Chamber claims that many of these communications are requests for legal advice, the excessive use of this description throughout the productions, without sufficient context, raised serious questions.

In addition, the Executive Chamber has seemingly extended the attorney-client privilege to shield communications from individuals who do not have an attorney-client relationship with the Executive Chamber. For instance, Linda Lacewell testified to the Select Committee that she was acting as Superintendent of DFS during the pandemic—a position that did not require the provision of legal advice to the Governor or the Executive Chamber—yet the Executive Chamber has asserted that communications with her are somehow protected by the attorney-client privilege.[1910] Ms. Lacewell testifies that in addition to her actual role as Superintendent, she also served as a counsel to the Executive Chamber and New York's COVID-19 Task Force.[1911] However, the Select Subcommittee disagrees there was an attorney-client relationship between Ms. Lacewell and the Executive Chamber or New York's COVID-19 Task Force.

An illustrative example of this is the following email the Executive Chamber marked as protected by both the deliberative process and attorney-client privileges.

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[1908] *Matter of Xerox Corp. v. Town of Webster*, 490 N.Y.S.2d 488 (N.Y. 1985).
[1909] NYSEC_SUBCOMM_00374033.
[1910] Lacewell TI, *supra* note 920.
[1911] Lacewell TI, *supra* note 920, at 11.

Subject: Re: NH report
Date: Saturday, June 27, 2020 at 11:00:36 AM Eastern Daylight Time
From: [redacted]
To: [redacted]
Attachments: image001.png

It was a q from MDR and reason for this morning's call.

Sent from my iPhone

On Jun 27, 2020, at 10:58 AM, [redacted] wrote:

ATTENTION: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.

And just so there is clarity here. The 10,000 deaths number should not be a surprise, shock, or anything to folks. It came from earlier drafts and analysis provide from you all to me that you worked on with McKinsey. On the briefing call going thru this data it was stated we needed to use the presumed and confirmed or the curve wouldn't work for the broader community spread argument, given testing was spotty at the beginning. I'm happy to remove that argument, which came from folks.

Below is the chart from the original McKinsey deck and was in the original draft provided by NYSDOH.
<image001.png.secure>

On 6/27/20, 10:13 AM, "[redacted] wrote:

Privileged and confidential
Attorney Work product

I'm getting more info but here's what I know so far:

1- on Re admissions we told doh to get the data for about 113 NH that hadn't responded to the survey. (I cleared with you MDR at the time). Instead of doing that, DOH reopened the survey for two days to ALL homes. We are getting who responded or Re-responded.

2- this proposed report includes the number of NH residents who died in hospitals. This number is not public. Instead of 6,500 deaths it would show 10,000 deaths.

3- Apparently latest draft (I haven't seen yet) says 30 percent antibodies in staff according to Bioreference. We need to make sure that's real and robust and defensible. DOH did not put that in and doesn't know anything about it.

4. "Causation" and "cause" are terms of art meaning proved by the data. Latest drafts use those terms incorrectly and we would be scoffed at. Requires edits.

5. If staff was sick it raises questions about providing PPE to nursing homes. We did a few large

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provisions but apparently we have never prioritized NHs for this and STILL do not. This is problematic. Adding Larry on this issue. We need to fix that. Megan has details.

When the Select Subcommittee asked the Executive Chamber to explain how this e-mail was protected from disclosure by attorney-client privilege, its counsel stated that numbers "4" and "5" were attorney communications, but that the principal rationale for withholding was deliberative process. Neither number "4" nor "5" appear to not fall under attorney-client privilege since they are not clearly the furnishing of legal advice. Further, the author of this e-mail marked it as "attorney-work product" which is distinguishable from attorney-client privilege. For attorney work product to apply, this e-mail must have been prepared during actual litigation or in anticipation of potential litigation. The State of New York has never taken the

position that litigation regarding the distribution of PPE to nursing homes was occurring or anticipated in June 2020.

The Select Subcommittee Had Limited Access to Additional Responsive Communications

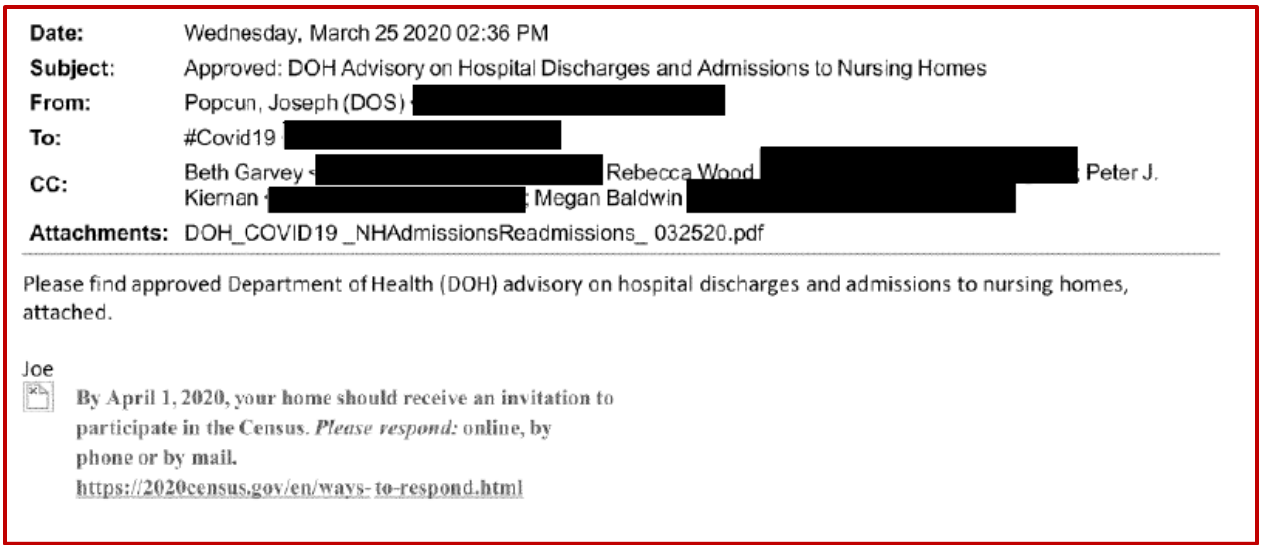
In a transcribed interview, Ms. Lacewell testified that Executive Chamber employees communicated through various means, including text messages and BlackBerry PIN messaging.[1912] Similarly, Mr. Cuomo testified to using BlackBerry PIN messaging to communicate with staff and conduct official business.[1913] Also, Ms. DeRosa testified that the former Governor didn't have an official email account and that BlackBerry PIN messaging was typically how she communicated with him.[1914]

Since the Select Subcommittee issued the subpoena, the Executive Chamber produced some BlackBerry PIN messages, although nearly all of them are from a two-month period in 2021 and arguably not responsive to the Select Subcommittee's investigation.[1915] When asked about the apparent discrepancy and lack of responsive material, Counsel for the Executive Chamber stated, "[w]e were working with the universe of documents we had and did not limit by date."[1916] The lack of availability of evidence hamstrung the Select Subcommittee's investigation.

Furthermore, the Executive Chamber has completely withheld certain responsive documents necessary to inform legislative action. For example, the Select Subcommittee is keenly interested to understand the decisions that led to the issuance of the March 25 Directive—including documents supporting claims it followed applicable federal guidance. This starts with understanding who was involved in developing, drafting, and issuing March 25 Directive. Accordingly, the November 6 Letter requested that the Executive Chamber produce "[a]ll documents and communications regarding or relating to the March 25, 2020 NYSDOH Advisory entitled, "Advisory: Hospital Discharges and Admission to Nursing Homes."[1917]

The only other email from March 25, 2020, produced by the Executive Chamber is the issuance of the Order.[1918] The email—which attached the Order—is limited to the following:

[1912] Lacewell TI, *supra* note 920.
[1913] Cuomo TI, *supra* note 907.
[1914] DeRosa TI, *supra* note 910.
[1915] As of December 4, 2024, the Executive Chamber identified additional BlackBerry PIN messages from other custodians and dating back to the beginning of the COVID-19 pandemic and stated its intent to produce additional BlackBerry PIN messages to the Select Subcommittee.
[1916] E-Mail from Stephen Juris, Counsel, Executive Chamber, New York State, to Select Subcomm. Staff (Nov. 9, 2024, 12:51 PM).
[1917] March 25 Directive.
[1918] NYSEC_SUBCOMM_00063814 (Email from Joseph Popcun, Department of State, New York State, to Beth Garvey, Special Counsel to the Governor, New York State, *et al*. (Mar. 25, 2020)).



Date: Wednesday, March 25 2020 02:36 PM
Subject: Approved: DOH Advisory on Hospital Discharges and Admissions to Nursing Homes
From: Popcun, Joseph (DOS) [redacted]
To: #Covid19 [redacted]
CC: Beth Garvey [redacted] Rebecca Wood [redacted] Peter J. Kiernan [redacted] Megan Baldwin [redacted]
Attachments: DOH_COVID19 _NHAdmissionsReadmissions_ 032520.pdf

Please find approved Department of Health (DOH) advisory on hospital discharges and admissions to nursing homes, attached.

Joe

By April 1, 2020, your home should receive an invitation to participate in the Census. *Please respond:* online, by phone or by mail.
https://2020census.gov/en/ways- to-respond.html

However, the privilege log produced by the Executive Chamber asserts that it was withholding this exact communication elsewhere in the production because it was protected by the deliberative process privilege, noting that it was an "[e]mail reflecting governmental deliberations regarding draft March 25, 2020 Advisory, attaching draft advisory reflecting governmental deliberations."[1919] This is another example of an inconsistency that leads to questions about the accuracy of the Executive Chamber's claims of privilege.

Similarly, the Select Subcommittee specifically requested all documents and communications regarding or relating to the NYSDOH Report.[1920] However, the documents provided by the Executive Chamber are insufficient. The Executive Chamber did not produce a single draft of the July 6 Report. Any documents containing drafts of the July 6 Report were provided to the Select Subcommittee by a whistleblower.

Despite its importance to our investigation, the Executive Chamber withheld all documents and communications related to the NYDOH Report between June 6, 2020 and July 6, 2020—the publication date of the report.[1921] These documents and communications included numerous priority custodians that we specifically requested, including Senior Executive Chamber staff.[1922] As noted previously, the Executive Chamber also withheld emails from McKinsey & Company[1923] and Michael Dowling, of Northwell Health, another individual identified as a priority custodian.[1924]

[1919] NYSEC_SUBCOMM_00374049.
[1920] New York State Department of Health, *Factors Associated with Nursing Home Infections and Fatalities in New York State During the COVID-19 Global Health Crisis*, (July 6, 2020), *available at* https://health.ny.gov/press/releases/2020/docs/nh_factors_report.pdf.
[1921] NYSEC_SUBCOMM_00374008-14; NYSEC_SUBCOMM_00374030; NYSEC_SUBCOMM_00374032; NYSEC_SUBCOMM_00374033; NYSEC_SUBCOMM_00374035-40; NYSEC_SUBCOMM_00374049; NYSEC_SUBCOMM_00374057-62; NYSEC_SUBCOMM_00374068; NYSEC_SUBCOMM_00374070-71; NYSEC_SUBCOMM_00374076; NYSEC_SUBCOMM_00374078.
[1922] *Id*.
[1923] *Supra*, n. 11.
[1924] *Supra*, n. 9.

The Executive Chamber is also withholding documents and communications involving nursing home data. For example, the Executive Chamber withheld an email thread between Melissa DeRosa, Linda Lacewell, and Megan Baldwin related to presumed nursing home fatalities.[1925] The privilege log claims these emails are an "[e]mail thread reflecting governmental deliberations regarding NYS information, attaching draft spreadsheet reflecting deliberations."[1926] It is highly concerning that the Executive Chamber would allege that nursing home death data could be interpreted as deliberative—facts are facts, facts and data are not deliberative.

In summary, the Executive Chamber has withheld responsive documents entirely and redacted some excessively without any proper legal basis. While the Select Subcommittee does not recognize attorney-client and deliberative process privileges, even if it did, the Executive Chamber's privilege log includes numerous privilege assertions that are ill-founded, inconsistent, or overly vague, all of which has impeded the Select Subcommittee's ability to challenge the asserted privileges.

[1925] NYSEC_SUBCOMM_00374014.
[1926] *Id*.